REGULATORY ASSESSMENT MICROFIELD™

Background

Discussions with Dr. Walter McGregor of Block Island Technologies, LLC (BIT) began in mid-February 2015, and at that time the product (Microfield™ lavage therapy and drainage system) was identified as a surgical drape. The question posed was whether or not the product required 510(k) clearance prior to marketing. Some descriptive information about the product was provided.

During a meeting on May 6, 2015, various documents found via a search by SDRS were reviewed including the products identified from search activities that seemed similar to the BIT product. By the May meeting, DICE had also responded to the requests regarding surgical drapes and this information was reviewed and discussed as well. During this meeting, the BIT product was referred to as an irrigation bag. A competitive product (irrigation bag – 3M Steri-Drape irrigation pouch) was obtained by BIT for the meeting and both products were compared. After the meeting, search activities resumed to determine the classification and product code for irrigation bags. No information was found at the FDA website related to the term "irrigation bag". A search of the Establishment Registration and Product listing database was conducted for 3M Steri-Drape products produced in Mexico (information acquired from the package label for the 3M product). The search resulted in the finding of Steri-Drape products all with the product classification code of KKX. FDA classification information at that time indicated that products under the code KKX were 510(k) exempt.

A report was issued on July 20, 2015 indicating no 510(k) was required. Later, a request was made for additional copies of the report as electronic copies and another search was conducted and an updated guidance document had been issued regarding FDA's intent to exempt certain Class II products from the 510(k) process. The original report was modified to cover this new guideline but did not change the assessment from the July report. The modified report was issued on October 12, 2015. The report issued on October 12, 2015, should be reviewed for full details on the search process and the outcome of the assessment. **We rely on this report to support the assessment that the product code, at that time, was KKX.**

On August 7, 2017, Dr. Walter McGregor requested a letter for a hospital interested in the product indicating that the product is 510(k) exempt. Because of the passage of time and because everything published by FDA was for "intent to exempt", I suggested a new search to determine the status of the various categories of surgical drape products. A new search uncovered new information issued by FDA.

This report focuses on the new information.

Product Code/Regulatory Identification

A new search was conducted for "surgical drapes" as covered by 221 CFR §878.4370, which is the only citation covering these types of products. The new product code listing is provided as **Attachment 1**. A number of product codes have been deleted by FDA but it is possible that

some of these were originally included in error (e.g., shave prep kit). Of importance is the fact that code KKX is not present and a new code "PUI" has been included.

A search of product codes KKX and PUI was conducted. Products under KKX now require a 510(k) while products under PUI do not. The printouts for these codes appear in **Attachments 2 and 3**, respectively. The PUI product code is the "exempt counterpart of KKX" and such products are exempt from the 510(k) requirement as long as they do not exceed the limitations of 21 CFR § 878.9 and do not include an antimicrobial agent. It has been confirmed with Dr. McGregor that the product does not contain an antibiotic. The citation for 221 CFR §878.9 is included in **Attachment 4.**

An additional search was undertaken to find the Federal Register Notice covering the exemption of certain Class II products. The Federal Register Notice is provided as **Attachment 5**. The Notice indicates that products without an antibiotic and in compliance with §878.9 are now covered under Product Code PUI – see Table 2 of that document.

Other Searches

In order to make sure nothing was overlooked, searches were repeated for the terms "Irrigation bag", "extremity bag" and "irrigation pouch" as was done for the earlier reports. Again, the search resulted in no records found. A search of Steri-Drape products manufactured by 3M in Mexico indicates the products are still listed as KKX. However, this is not unexpected because the Federal Register Notice was not published until July 11, 2017. The result of these searches are provided in **Attachment 6**.

Need for a 510(k)

Based on the information in the Federal Register notice and because the product does not contain an antibiotic, no 510(k) is required, assuming compliance with §890.0. FDA will review the status of these exempted products at least every 5 years or sooner, if needed. Periodic assessment on the part of BIT should be performed.

Product Regulatory Requirements

Although at this point a 510(k) is not required, there are other regulatory requirements in order to market the product. The list below contains some significant requirements but may not be an all-inclusive list. BIT is urged to have further discussion with the contract manufacturer and distributor on additional requirements including State requirements.

Recognized Consensus Standards

The document covering PUI (**Attachment 3)** no longer lists standards to be met. However, the standards in **Attachment 2** for KKX may be helpful regarding testing for your product. With regard to biocompatibility testing, you must have data to prove the product can be in contact with breached or compromised skin for up to 24 hours. Data may be available from the supplier of the material used to form the bag. Additionally, bench testing is needed to make sure the product will perform as required (e.g., will not burst during use).

Sterilization and Shelf Life
Your product is sold sterile and so you must do validation at the appropriate time. Your sterilization facility will be able to provide this service and a final report on the validation. You may need to place the product on stability. You should take this issue up with the manufacturer and sterilizer. If you require a consultant to advise you on this matter, SDRS LLC may be able to provide some contacts. At the very least, you need data to support that the packaging remains intact for the expiration period, if one is listed on your label.

Other Regulatory Requirements

Manufacturing
The product must be manufactured under GMP conditions.

Registration and Listing
Certain registrations and listings are required. BIT should register as a specification holder. The contract manufacturer must be registered. The contract sterilizer must be registered. The product must be device listed. Take this up with your contract manufacturer or distributor because they may be able to list on your behalf. If not, BIT can handle the device listing as the specification holder and you should use product code: PUI. The product will also need a Universal Device Identifier (UDI) and this can be supplied by either the manufacturer or distributor. **However, this should be discussed with them early on in case BIT has to develop the UDI.**

Handling of Complaints/Recalls
You have a requirement to have certain services available; however, you can assign them to the manufacturer and/or distributor or contract these out to a service provider.

> Product complaints, such as leaking, bag breakage, package not intact, etc, are complaints that have to be addressed including the possible testing of returned product and/or reserved samples or materials to determine if there is a design or manufacturing flaw, etc., or if there is a need for a recall or market correction, etc.
>
> Based on complaints or other communications from suppliers or users, there could be a recall situation and BIT, the manufacturer, distributor or a contract service provider needs to be available to handle this.
>
> There could be complaints of adverse events and these must be investigated and certain types of adverse events have to be reported to the FDA. There are contract facilities available to handle these activities.
>
> For potential recalls, if the manufacturer or distributor cannot handle such an event, you should identify contract services so if the need arises, BIT can react quickly.

21 CFR §890.9

Earlier in this document, a citation to the Code of Federal Regulations, 21 CFR §890.9, was referenced.

The following two situations require the filing of a 510(k) even if an exemption has been granted.

> (a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;
> (b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or [the remainder relates to in-vitro devices].

The first paragraph is critical. Your product labeling or advertising could cause the FDA to make a determination that the product is outside the scope of the exemption. Thus, you must be careful with any claims made and these should be limited to obvious product features e.g., clear plastic – easy to visualize procedure, affixes with string tie and not adhesive. BIT may find products in the marketplace making various significant claims; however, BIT must be mindful that these claims may be allowed because the competitor has provided data that the FDA found acceptable during 510(k) review.

Recommendation for Changing the Common Name

The designated common name should be in agreement with the code PUI, which at present appears to be “surgical drape”. However, use of the term irrigation bag (same as the 3M product) may also be acceptable. The present common name, lavage therapy and drainage system, should be changed. The terms “therapy” and “system” could result in an FDA determination that the product exceeds the limitations of the exemption (21 CFR §890.9), covered above.

FDA

Product Classification

1 to 8 of 8 Results

510(K) Exempt Device Class 2 878.4370

Results per Page 10

New Search

Export to Exc

Product Code	Device		Regulation Number	Device Class
HMW	Drape, Microscope, Ophthalmic	Surgical Drape And Drape Accessories	878.4370	
HMT	Drape, Patient, Ophthalmic	Surgical Drape And Drape Accessories	878.4370	
EYX	Drape, Pure Latex Sheet, With Self-Retaining Finge ...	Surgical Drape And Drape Accessories	878.4370	
ERY	Drape, Surgical, Ent	Surgical Drape And Drape Accessories	878.4370	
PUI	Drape, Surgical, Exempt	Surgical Drape And Drape Accessories	878.4370	
EYY	Drape, Urological, Disposable	Surgical Drape And Drape Accessories	878.4370	
FNW	Pad, Kelly	Surgical Drape And Drape Accessories	878.4370	
KGW	Ring (Wound Protector), Drape Retention, Internal	Surgical Drape And Drape Accessories	878.4370	

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/cfdocs/search/default.cfm?FAQ=true
7. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=ProductCode
8. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=ProductCodeDESC
9. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=DeviceName
10. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=DeviceNameDESC
11. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=RegulationNumber
12. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=RegulationNumberDESC
13. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=DeviceClass
14. ../cfpcd/classification.cfm?start_search=1&Submission_Type_ID=4&DeviceName=&ProductCode=&DeviceClass=2&ThirdParty=&Panel=&Re 2E4370&Implant_Flag=&Life_Sustain_Support_Flag=&PAGENUM=10&sortcolumn=DeviceClassDESC

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Product Classification

New Search Back To Search Results

Device	Drape, Surgical
Regulation Description	Surgical drape and drape accessories.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	KKX
Premarket Review	Office of Device Evaluation[6](ODE) Division of Surgical Devices (DSD) Plastic and Reconstructive Surgery Devices Branch Two - Skin/Wound Dressing/Aesthetic Injectables (PRSB2)
Submission Type	510(k)
Regulation Number	878.4370[7]
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report[8]
GMP Exempt?	No

Recognized Consensus Standards

6-217 ASTM F1670-08/F1670M-08 (Reapproved 2014)
Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood[9]

6-296 AAMI ANSI PB70:2012
Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities[10]

6-306 ASTM F1671/F1671M-13
Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System[11]

Guidance Document

Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes (PDF)[12]

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

Eligible for *Accredited Persons Expansion Pilot Program*[13]

Accredited Persons

Regulatory Technology Services, Llc[14]
Third Party Review Group, Llc[15]
Tuv Sud America Inc.[16]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.ht
6. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH
7. /scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=878.4370
8. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=5580
9. /scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=32729
10. /scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=30973
11. /scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31764
12. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidance
13. https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdev
14. /scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm?party_key=4#top
15. /scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm?party_key=7#top
16. /scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm?party_key=2#top

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Product Classification

New Search Back To Search Results

Device	Drape, Surgical, Exempt
Regulation Description	Surgical drape and drape accessories.
Definition	This product code is the class ii exempt counterpart of kkx, and was exempted, subject to the limitations of exemption, under the procedures established by the 21st century cures act.This device type does not require premarket notification (510(k)) to market if it does not exceed the general limitations of exemption found in 21 cfr 878.9 and the specific limitations of exemption as stated in the "physical state" field of this product code description.
Physical State	Exemption is limited to surgical drapes that do not include an antimicrobial agent.
Technical Method	This product code is the class II exempt counterpart of KKX, and was exempted, subject to the limitations of exemption, under the procedures established by the 21st Century Cures Act. This device type does not require premarket notification (510(k)) to market if it does not exceed the general limitations of exemption found in 21 CFR 878.9 and the specific limitations of exemption as stated in the "Physical State" field of this product code description.
Target Area	This product code is the class II exempt counterpart of KKX, and was exempted, subject to the limitations of exemption, under the procedures established by the 21st Century Cures Act. This device type does not require premarket notification (510(k)) to market if it does not exceed the general limitations of exemption found in 21 CFR 878.9 and the specific limitations of exemption as stated in the "Physical State" field of this product code description.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	PUI
Premarket Review	Office of Device Evaluation[6](ODE) Division of Surgical Devices (DSD) Plastic and Reconstructive Surgery Devices Branch Two - Skin/Wound Dressing/Aesthetic Injectables (PRSB2)
Submission Type	510(K) Exempt
Regulation Number	878.4370[7]
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report[8]
GMP Exempt?	No

Note: Class II devices the Food and Drug Administration (FDA) has also

published a list of Class II (special controls) devices[9] subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.ht
6. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH
7. /scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=878.4370
8. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=5743
9. /scripts/cdrh/cfdocs/cfpcd/315.cfm

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

FDA

CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2016.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2016]
[CITE: 21CFR890.9]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 890 -- PHYSICAL MEDICINE DEVICES

Subpart A--General Provisions

Sec. 890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from

clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. http://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl
7. /scripts/cdrh/cfdocs/search/default.cfm?FAQ=true
8. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm
9. /scripts/cdrh/devicesatfda/index.cfm?Search_Term=Limitations%20of%20exemptions%20from%20section%20510%28k%29%20of%20the%20Federal%20Food%2C%20Drug%2C%20and%20Cosmetic%20Act%20%28the%20act%29%2E

Page Last Updated: 09/21/2016

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

New Search No records were found with **Device Name:** *irrigation bag* **Decision Date To:** *08/09/2017*

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

New Search No records were found with **Device Name:** *extremity bag* **Decision Date To:** *08/09/2017*

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

New Search No records were found with **Device Name:** *irrigation pouch* **Decision Date To:** *08/09/2017*

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Proprietary Name:	3M¿ Ioban¿ 2; 3M¿ Steri-Drape¿ Ioban¿ 2
Classification Name:	DRAPE, SURGICAL
Product Code:	KKX[6]
Device Class:	2
Regulation Number:	878.4370[7]
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	3M EDUMEX, S.A DE C.V[8]
Registered Establishment Number:	9680284
Premarket Submission Number:	K801550[9]
Owner/Operator:	3M COMPANY, 3M HEALTH CARE[10]
Owner/Operator Number:	2110898
Establishment Operations:	Manufacturer

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. ../cfPCD/classification.cfm?ID=5580
7. ../cfCFR/CFRsearch.cfm?FR=878.4370
8. ../cfRL/rl.cfm?rid=5715
9. ../cfpmn/pmn.cfm?id=K801550
10. ../cfRL/rl.cfm?start_search=1&OwnerOperatorNumber=2110898

Page Last Updated: 08/07/2017

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Site Map Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of **Health & Human Services**

Links on this page:

human tests to begin became effective on March 10, 1997. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on March 5, 1997, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the biological device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 29, 2013. The applicant claims December 23, 2013, as the date the premarket approval application (PMA) for INTERCEPT BLOOD SYSTEM FOR PLASMA (PMA BP130076) was initially submitted. However, FDA records indicate that the complete PMA BP130076 was submitted on November 29, 2013.

3. *The date the application was approved:* December 16, 2014. FDA has verified the applicant's claim that PMA BP130076 was approved on December 16, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,860 days or 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in 21 CFR 60.30, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (see **ADDRESSES**).

Dated: July 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–14454 Filed 7–10–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1129]

Medical Devices; Exemptions From Premarket Notification: Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a list of class II devices that the Agency has determined based on established factors to no longer require premarket notification to provide reasonable assurance of safety and effectiveness, subject to certain limitations. FDA is publishing this notice of that determination in accordance with procedures established by the 21st Century Cures Act. This notice represents FDA's final determination with respect to the list of class II devices proposed in a March 14, 2017, **Federal Register** document. The exemptions in this notice will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations.

FOR FURTHER INFORMATION CONTACT: Bryce Bennett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993, email: *Gregory.Bennett@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 14, 2017 (82 FR 13609), FDA issued a notice proposing to exempt a list of class II devices from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)), subject to certain limitations. This notice was issued in accordance with the 21st Century Cures Act (Pub. L. 114–255), which was signed into law on December 13, 2016. Section 3054 of that statute amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act provides that, within 90 days after enactment of the 21st Century Cures Act and at least once every 5 years thereafter, FDA must publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act (generally referred to as a premarket notification or ''510(k)'') to provide reasonable assurance of safety and effectiveness. Within 210 days of enactment of the 21st Century Cures Act, FDA must publish in the **Federal Register** a list representing its final determination regarding the list of devices proposed in the March 14, 2017, notice. Section 510(m)(3) of the FD&C Act provides that upon the date that this final list is published in the **Federal Register**, a 510(k) will no longer be required for the listed devices and the applicable classification regulation for these devices shall be deemed amended to incorporate such exemption. Interested persons were given until May 15, 2017, to comment on the proposed list of class II devices. After reviewing these comments and considering whether the proposed list should be modified, FDA is now identifying its final determination as to which of those devices are now exempt from premarket notification requirements, subject to certain limitations, as indicated in tables 1 to 3 of this notice.

In a future action, FDA intends to amend the codified language for each listed device's classification regulation to reflect this final determination. Persons with pending 510(k) submissions for devices that are now exempt from premarket notification, subject to the limitations on exemptions, should withdraw their submissions.

These exemptions will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulation. Specifically, regulated industry will no longer have to invest time and resources in premarket notifications, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (Ref. 1).

III. Limitations on Exemptions

FDA believes that the types of class II devices listed in this notice should be exempt from the premarket notification requirements found under section 510(k) of the FD&C Act. However, an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's determination that premarket notification is unnecessary to provide a reasonable assurance of safety and effectiveness for devices listed in this document is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

In addition to being subject to the general limitations to the exemptions found in Title 21 of the Code of Federal Regulations (CFR) sections 862.9 to 892.9 (§§ 862.9 to 892.9), when Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices in a particular group, FDA may partially limit the exemption from premarket notification requirements to specific devices within a listed device type. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices. Partial exemption limitations can be found in table 2 of this notice. FDA has assigned new product codes to the device types that are now exempt subject to the partial limitations in order to ensure that these devices can be separated from devices that do not fall within the partial exemption limitation under the existing product code (*i.e.,* exempt and non-exempt devices within a device type will have distinct product codes). If table 2 indicates that a partial exemption limitation does apply to a device, then affected device manufacturers should review their registration and listing information to assess if they should list their device using the original classification product code, which requires premarket notification, or the new classification product code for the subset of that device type that is now 510(k) exempt (subject to the general limitations to the exemptions found in §§ 862.9 to 892.9). In table 2, for example, FDA is listing the exemption of the tympanometer but limits the exemption to such devices that are in compliance with FDA-recognized consensus standard ANSI S3.39. Tympanometers that comply with this partial exemption limitation and the corresponding general limitations in § 874.9 are now exempt from the 510(k) requirements and should be identified under new product code ''PTP'' in subsequent registration and listing submissions. However, tympanometers not in compliance with each of these exemption limitations remain subject to the 510(k) requirements and will retain product code ''NAS.'' We recommend that device manufacturers document in their records any changes in the product code of their device with appropriate justification.

IV. List of Class II Devices

In table 1, FDA is identifying the following list of class II devices that no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in §§ 862.9 to 892.9:

TABLE 1—CLASS II DEVICES

21 CFR section	Device type	Product code
862.1020	Acid Phosphatase, Nitrophenylphosphate	CJN
862.1020	Acid Phosphatase, Thymol Blue Monophosphate	CJR
862.1020	Acid Phosphatase, Disodium Phenylphosphate	CJX
862.1020	Acid Phosphatase, Naphthyl Phosphate	CKB
862.1020	Acid Phosphatase, Thymolphthale Inmonophosphate	CKE
862.1020	Acid Phosphatase, Beta Glycerophosphate	CKH
862.1020	Acid Phosphatase (Prostatic), Tartrate Inhibited	JFH
862.1090	Radioassay, Angiotensin Converting Enzyme	KQN
862.1100	Vanillin Pyruvate, AST/SGOT	CIF
862.1100	Diazo, AST/SGOT	CIQ
862.1100	Hydrazone Colorimetry, AST/SGOT	CIS
862.1100	NADH Oxidation/NAD Reduction, AST/SGOT	CIT
862.1150	Calibrator, Primary	JIS
862.1150	Calibrator, Secondary	JIT
862.1150	Calibrator, Surrogate	JIW
862.1150	Calibrator, Multi-Analyte Mixture	JIX
862.1345	Drink, Glucose Tolerance	MRV
862.1350	Continuous Glucose Monitor Secondary Display	PJT
862.1445	Chromatographic Separation, Lactate Dehydrogenase Isoenzymes	CEX
862.1445	Electrophoretic, Lactate Dehydrogenase Isoenzymes	CFE
862.1445	Differential Rate Kinetic Method, Lactate Dehydrogenase Isoenzymes	JGF
862.1509	System, Test, Urinary Methylmalonic Acid	LPT
862.1685	Radioimmunoassay, Thyroxine-Binding Globulin	CEE
862.1700	Radioimmunoassay, Total Thyroxine	CDX
862.1700	Enzyme Immunoassay, Non-Radiolabeled, Total Thyroxine	KLI
862.2265	High Throughput DNA Sequence Analyzer	PFF
862.2570	Instrumentation For Clinical Multiplex Test Systems	NSU
862.2570	Real Time Nucleic Acid Amplification System	OOI
862.2570	Mass Spectrometer For Clinical Multiplex Test Systems	OTA
862.2570	Micro Total Analysis Instrument System	OUE
862.2570	Complete Gene Expression Profiling Accessory Reagents	OVA
862.2570	DNA Genetic Analyzer	PCA
862.2570	Data Acquisition Software	PQQ
862.3200	Calibrators, Drug Mixture	DKB
862.3200	Calibrators, Drug Specific	DLJ

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code
862.3200	Calibrators, Ethyl Alcohol	DNN
864.5400	Fibrometer	GIE
864.5400	Timer, Coagulation	JBT
864.5425	Control, Plasma, Abnormal	GGC
864.5425	Plasma, Coagulation Control	GGN
864.5425	Plasma, Control, Normal	GIZ
864.6550	Control, Fecal Occult Blood	OSL
864.6650	Study, Platelet Adhesive	JBZ
864.7275	Test, Euglobulin Lysis	JBO
864.7300	Fibrin Monomer Paracoagulation	JBN
864.7340	Fibrinogen Standard	GFX
864.7340	Plasma, Fibrinogen Control	GIL
864.7375	Glutathione, Red-Cell	GII
864.7375	Fluorescence, Visual Observation (Qual., U.V.), Glutathione Reductase	JMH
864.7375	Assay, Glutathione Reductase	KQF
864.7415	Control, Hemoglobin, Abnormal	JCM
864.7455	Stain, Fetal Hemoglobin	GHQ
864.7500	Acid Hematin	GGF
864.7720	Test, Prothrombin Consumption	GGQ
864.7735	Prothrombin-Proconvertin and Thrombotest	JPF
864.8150	Calibrator for Cell Indices	KRX
864.8165	Calibrator for Hemoglobin and Hematocrit Measurement	KRZ
864.8175	Calibrator for Platelet Counting	KRY
864.8185	Calibrator for Red-Cell and White-Cell Counting	KSA
864.8625	Standards and Controls, Hemoglobin, Normal and Abnormal	GFS
864.8625	Control, White-Cell	GGL
864.8625	Control, Hemoglobin	GGM
864.8625	Control, Platelet	GJP
864.8625	Control, Red-Cell	GJR
864.8625	Control, Hematocrit	GLK
864.8625	Mixture, Control, White-Cell and Red-Cell Indices	GLQ
864.8625	Control, Cell Counter, Normal and Abnormal	JCN
864.8625	Mixture, Hematology Quality Control	JPK
864.8625	Material, Quality Control, Semen Analysis	NRF
864.8625	Control Material, Blood Circulating Epithelial Cancer Cell	NRS
864.9400	Solution, Stabilized Enzyme	KSK
866.3395	Norovirus Serological Reagents	OUC
866.5210	Immunochemical, Ceruloplasmin	CHN
866.5210	Ceruloplasmin, Rhodamine, Antigen, Antiserum, Control	DCT
866.5210	Ceruloplasmin, FITC, Antigen, Antiserum, Control	DCY
866.5210	Ceruloplasmin, Antigen, Antiserum, Control	DDB
866.5210	P-Phenyl-Enediamine/EDTA (Spectrophotometric), Ceruloplasmin	JFQ
866.5210	Indirect Copper Assay, Ceruloplasmin	JFR
866.5470	Hemoglobin, Chain Specific, Antigen, Antiserum, Control	DAM
866.5620	*Alpha*-2-Macroglobulin, Rhodamine, Antigen, Antiserum, Control	DDT
866.5620	*Alpha*-2-Macroglobulin, FITC, Antigen, Antiserum, Control	DDY
866.5620	*Alpha*-2-Macroglobulin, Antigen, Antiserum, Control	DEB
866.5630	System, Test, *Beta*-2-Microglobulin Immunological	JZG
866.5910	Quality Control Material, Genetics, DNA	NZB
868.1040	Algesimeter, Powered	BSI
868.1400	Legging, Compression, Non-Inflatable	LLK
868.2500	Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia	KLK
868.2500	Monitor, Oxygen, Cutaneous, For Uses Other Than For Infant Not Under Gas Anesthesia	LPP
868.2550	Pneumotachometer	JAX
868.5180	Bed, Rocking, Breathing Assist	CCO
868.6250	Compressor, Air, Portable	BTI
870.1390	Trocar	DRC
870.1875	Lung Sound Monitor	OCR
870.2675	Oscillometer	DRZ
870.4280	Filter, Prebypass, Cardiopulmonary Bypass	KRJ
870.4290	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass	DTL
870.4340	Monitor and/or Control, Level Sensing, Cardiopulmonary Bypass	DTW
870.4420	Sucker, Cardiotomy Return, Cardiopulmonary Bypass	DTS
870.4430	Suction Control, Intracardiac, Cardiopulmonary Bypass	DWD
872.1720	Tester, Pulp	EAT
872.3260	External Cleaning Solution	PME
872.3300	Coating, Denture Hydrophilic, Resin	EBE
872.3540	Pad, Denture, Over The Counter	EHR
872.3540	Cushion, Denture, Over The Counter	EHS
872.3560	Reliner, Denture, Over The Counter	EBP
872.3590	Denture, Plastic, Tooth	ELM

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code
872.3600	Denture Preformed (Partially Prefabricated Denture)	EKO
872.3890	Splint, Endodontic Stabilizing	ELS
872.5550	Ring, Teething, Fluid-Filled	KKO
872.6770	Syringe, Cartridge	EJI
874.1120	Generator, Electronic Noise (for Audiometric Testing)	ETS
874.1325	Electroglottograph	KLX
874.3310	Calibrator, Hearing Aid/Earphone and Analysis Systems	ETW
874.3320	Hearing Aid, Group and Auditory Trainer	EPF
874.3320	Device, Assistive Listening	LZI
874.3330	Hearing Aid, Master	KHL
874.3430	Mold, Middle-Ear	ETC
874.3730	Device, Voice Amplification	MCK
876.1500	Light Source, Incandescent, Diagnostic	FCQ
876.1500	Light Source, Photographic, Fiberoptic	FCR
876.1500	Light Source, Fiberoptic, Routine	FCW
876.1500	Carrier, Sponge, Endoscopic	FGS
876.1500	Light Source, Endoscope, Xenon Arc	GCT
876.1500	Transformer, Endoscope	GCW
876.1500	LED Light Source	NTN
876.1500	Endoscopic Guide Wire, Gastroenterology-Urology	OCY
876.4020	Light, Catheter, Fiberoptic, Glass, Ureteral	FCS
876.4270	Rod, Colostomy	EZP
876.4400	Ligator, Hemorrhoidal	FHN
876.4400	Ligator, Esophageal	MND
876.4500	Lithotriptor, Biliary Mechanical	LQC
876.4770	Urethrotome	EZO
876.5010	Bag, Bile Collecting	EXF
876.5025	Vibrator for Climax Control of Premature Ejaculation	PIA
876.5365	Dilator, Esophageal (Metal Olive) Gastro-Urology	EZM
876.5365	Bougie, Esophageal, and Gastrointestinal, Gastro-Urology	FAT
876.5365	Dilator, Esophageal	KNQ
876.5520	Dilator, Urethral	KOE
876.5665	Disinfectant, Subsystem, Water Purification	NIH
876.5820	Set, Dialyzer Holder	FKI
876.5895	Irrigator, Ostomy	EXD
876.5980	Catheter, Retention, Barium Enema With Bag	FGD
876.5980	Gastrostomy Tube Holder	PLI
878.4370	Drape, Surgical, ENT	ERY
878.4370	Drape, Pure Latex Sheet, With Self-Retaining Finger Cot	EYX
878.4370	Drape, Urological, Disposable	EYY
878.4370	Pad, Kelly	FNW
878.4370	Drape, Patient, Ophthalmic	HMT
878.4370	Drape, Microscope, Ophthalmic	HMW
878.4370	Ring (Wound Protector), Drape Retention, Internal	KGW
878.4580	Lamp, Operating-Room	FQP
878.4580	Light, Surgical, Instrument	FSQ
878.4580	Light, Surgical, Floor Standing	FSS
878.4580	Light, Surgical, Endoscopic	FSW
878.4580	Light, Surgical, Connector	FSX
878.4580	Light, Surgical, Ceiling Mounted	FSY
878.4580	Light, Surgical, Carrier	FSZ
878.4580	Light, Surgical, Accessories	FTA
878.4580	Lamp, Surgical	FTD
878.4580	Illuminator, Remote	FTG
878.4580	Lamp, Surgical, Incandescent	GBC
878.5070	Apparatus, Air Handling, Bench	FZG
878.5070	Apparatus, Air Handling, Room	FZH
878.5070	Apparatus, Air Handling, Enclosure	FZI
880.5580	Locator, Acupuncture Point	BWJ
880.5580	Needle, Acupuncture, Single Use	MQX
880.5780	Stocking, Medical Support (to Prevent Pooling of Blood in Legs)	DWL
882.1020	Analyzer, Rigidity	GZM
882.1540	Device, Galvanic Skin Response Measurement	GZO
882.1560	Device, Skin Potential Measurement	HCJ
882.1855	Encephalogram Telemetry System	GYE
882.5895	Vibratory Counter-Stimulation	OVP
884.2990	Sheet, Recording, Breast Examination	NHM
884.3200	Drain, Cervical	HFL
884.4400	Forceps, Obstetrical	HDA
884.4530	Clamp, Umbilical	HFW
884.4530	Speculum, Vaginal, Nonmetal	HIB

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code
884.4530	Speculum, Vaginal, Nonmetal, Fiberoptic	HIC
884.4530	Clamp and Cutter, Umbilical	NBZ
884.4900	Table, Obstetrical, AC-Powered (and Accessories)	HDD
884.4900	Table, Obstetrical, Manual (and Accessories)	HHP
884.4900	Table, Obstetric (and Accessories)	KNC
884.5200	Hemorrhoid Prevention Pressure Wedge	OOA
884.5390	Heater, Perineal, Direct Contact	HGZ
884.5390	Heater, Perineal, Radiant, Non-Contact	HHA
884.5390	Heater, Perineal	KND
884.5400	Cup, Menstrual	HHE
884.5425	Pad, Menstrual, Scented	HHL
884.6150	Micromanipulators and Microinjectors, Assisted Reproduction	MQJ
886.1120	Photorefractor	MMF
886.1120	Camera, Ophthalmic, General-Use	PJZ
886.1250	Euthyscope, AC-Powered	HMK
886.1570	Ophthalmoscope, AC-Powered	HLI
886.1570	Ophthalmoscope, Battery-Powered	HLJ
886.1570	Ophthalmoscopes, Replacement Batteries, Hand-Held	MSG
886.1780	Retinoscope, AC-Powered	HKL
886.1945	Transilluminator, AC-Powered	HJM
886.4150	Tubing, Replacement, Phacofragmentation Unit	MSR
886.4250	Unit, Electrolysis, AC-Powered, Ophthalmic	HRO
886.4335	Headlight, Fiberoptic Focusing	FCT
886.4335	Light, Headband, Surgical	FSR
886.4335	Headlamp, Operating, AC-Powered	HPQ
886.4400	Locator, Metal, Electronic	HPM
886.4440	Magnet, AC-Powered	HPO
886.4790	Sponge, Ophthalmic	HOZ
886.4790	Eye Tray	OJK
888.1240	Dynamometer, AC-Powered	LBB
888.4580	Instrument, Surgical, Sonic and Accessory/Attachment	JDX
888.4580	System, Cement Removal Extraction	LZV
890.1450	Hammer, Reflex, Powered	IKO
890.5100	Bath, Hydro-Massage	ILJ
890.5100	Bath, Sitz, Powered	ILM
890.5110	Bath, Paraffin	IMC
890.5250	Cabinet, Moist Steam	IMB
890.5360	Exerciser, Measuring	ISD
890.5500	Lamp, Infrared, Therapeutic Heating	ILY
890.5575	Device, Warning, Overload, External Limb, Powered	IRN
892.1000	MRI Disposable Kit	OIM
892.1560	Biopsy Needle Guide Kit	OIJ
892.1610	Aperature, Radiographic	IZS
892.1610	Cone, Radiographic	IZT
892.1610	Collimator, Automatic, Radiographic	IZW
892.1610	Collimator, Manual, Radiographic	IZX
892.1610	Device, Beam Limiting, X-Ray, Diagnostic	KPW
892.1650	Arthrogram Tray	OII
892.1650	Radiology Dental Tray	OIK
892.1670	Device, Spot-Film	IXL
892.1680	Radiographic Contrast Tray	OIO
892.1680	Radiology Diagnostic Kit	OIP
892.1730	Discography Kit	OIL
892.1820	Chair, Pneumocephalographic	HBK
892.1850	Cassette, Radiographic Film	IXA
892.1860	Changer, Radiographic Film/Cassette	KPX
892.1870	Programmer, Changer, Film/Cassette, Radiographic	IZP
892.1900	Controller, Temperature, Radiographic	EGT
892.1900	Dryer, Film, Radiographic	EGW
892.1900	Processor, Radiographic-Film, Automatic, Dental	EGY
892.1900	Processor, Radiographic-Film, Automatic	IXW
892.1900	Processor, Cine Film	IXX
892.2030	Digitizer, Image, Radiological	LMA
892.2030	Digitizer, Images, Ophthalmic	NFH
892.2040	Camera, Multi Format, Radiological	LMC
892.2040	Device, Hardcopy, Images, Ophthalmic	NFI
892.5730	Prostate Seeding Kit	OIN

In table 2, FDA is identifying a list of class II devices that no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in §§ 862.9 to 892.9, as well as the indicated partial exemption limitations. Devices listed in table 2 are now exempt, but only if they are in concurrent compliance with both the partial exemption limitation specified in table 2 and its corresponding general limitation found in the .9 section of Parts 862 to 892 of Title 21 of the CFR.

TABLE 2—CLASS II DEVICES

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3100	Enzyme Immunoassay, Amphetamine.	PUX	DKZ	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3100	Radioimmunoassay, Amphetamine.	PUX	DJP	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3100	Thin Layer Chromatography, Amphetamine.	PUX	DIT	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3100	Gas Chromatography, Amphetamine.	PUX	DOD	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3100	Liquid Chromatography, Amphetamine.	PUX	DNI	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3100	Free Radical Assay, Amphetamine.	PUX	DJL	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3150	Enzyme Immunoassay, Barbiturate.	PUY	DIS	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3150	Radioimmunoassay, Barbiturate.	PUY	DKN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3150	Thin Layer Chromatography, Barbiturate.	PUY	DKX	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3150	Mercury Dithiazone, Colorimetry, Barbiturate.	PUY	DJN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3150	Hemagglutination Inhibition, Barbiturate.	PUY	DLX	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3150	Gas Liquid Chromatography, Barbiturate.	PUY	DMF	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3150	High Pressure Liquid Chromatography, Barbiturate.	PUY	KZY	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3170	Enzyme Immunoassay, Benzodiazepine.	PUZ	JXM	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3170	High Pressure Liquid Chromatography, Benzodiazepine.	PUZ	LAA	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3170	Test, Benzodiazepine, Over The Counter.	PUZ	NFV	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3170	Gas Chromatography, Benzodiazepine.	PUZ	KZZ	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3170	Thin Layer Chromatography, Benzodiazepine.	PUZ	LAB	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Enzyme Immunoassay, Cocaine and Cocaine Metabolites.	PVA	DIO	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Radioimmunoassay, Cocaine Metabolite.	PVA	KLN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Enzyme Immunoassay, Cocaine.	PVA	JXO	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Hemagglutination, Cocaine Metabolites (Benzoylecgonine).	PVA	DLN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Thin Layer Chromatography, Cocaine.	PVA	DMN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3250	Free Radical Assay, Cocaine	PVA	DIR	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Gas Chromatography, Cocaine.	PVA	DIN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	Thin Layer Chromatography, Benzoylecgonine.	PVA	DOM	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3250	High Pressure Liquid Chromatography, Cocaine and Cocaine Metabolites.	PVA	LAC	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3270	High Pressure Liquid Chromatography, Codeine.	PVB	LAE	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3270	Thin Layer Chromatography, Codeine.	PVB	DLD	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3270	Gas Chromatography, Codeine.	PVB	LAD	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3580	Radioimmunoassay, LSD (125–I).	PVC	DLB	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3580	Free Radical Assay, LSD	PVC	DOL	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3610	Gas Chromatography, Methamphetamine.	PVD	LAF	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3610	Thin Layer Chromatography, Methamphetamine.	PVD	DJC	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3610	High Pressure Liquid Chromatography, Methamphetamine.	PVD	LAG	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3610	Test, Methamphetamine, Over The Counter.	PVD	NGG	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3620	Enzyme Immunoassay, Methadone.	PVE	DJR	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3620	Hemagglutination Inhibition, Methadone.	PVE	DIW	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3620	Gas Chromatography, Methadone.	PVE	DMB	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3620	Thin Layer Chromatography, Methadone.	PVE	DKR	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3620	Liquid Chromatography, Methadone.	PVE	DNT	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3620	Free Radical Assay, Methadone.	PVE	DPP	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3630	Radioimmunoassay, Methaqualone.	PVF	KXS	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Thin Layer Chromatography, Morphine.	PVG	DNK	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Radioimmunoassay, Morphine (123–I), Goat Antibody Ammonium Sulfate Sep..	PVG	DOE	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Fluorometry, Morphine	PVG	DJJ	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Liquid Chromatography, Morphine.	PVG	DPK	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3640	Gas Chromatography, Morphine.	PVG	DMY	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Hemagglutination Inhibition, Morphine.	PVG	DLR	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Free Radical Assay, Morphine.	PVG	DOK	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Radioimmunoassay, Morphine (3–H), Goat Antibody Ammonium Sulfate Sep..	PVG	DIQ	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3640	Radioimmunoassay, Morphine-Barbiturate (125–I), Goat Antibody.	PVG	DNA	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3650	Enzyme Immunoassay, Opiates.	PVH	DJG	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3650	Gas Chromatography, Opiates.	PVH	DJF	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3650	Hemagglutination, Opiates	PVH	DLT	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3650	Thin Layer Chromatography, Opiates.	PVH	LAI	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3650	Free Radical Assay, Opiates	PVH	DKT	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3650	High Pressure Liquid Chromatography, Opiates.	PVH	LAH	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3700	Enzyme Immunoassay, Propoxyphene.	PVI	JXN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3700	Thin Layer Chromatography, Propoxyphene.	PVI	DPN	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3700	Gas Chromatography, Propoxyphene.	PVI	LAJ	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3700	High Pressure Liquid Chromatography, Propoxyphene.	PVI	LAK	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3870	Enzyme Immunoassay, Cannabinoids.	PVJ	LDJ	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
862.3870	Reagents, Test, Tetrahydrocannabinol.	PVJ	DKE	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3870	Radioimmunoassay, Cannabinoid(S).	PVJ	LAT	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3910	High Pressure Liquid Chromatography, Tricyclic Antidepressant Drugs.	PVK	LFI	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3910	U.V. Spectrometry, Tricyclic Antidepressant Drugs.	PVK	LFH	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
862.3910	Thin Layer Chromatography, Tricyclic Antidepressant Drugs.	PVK	MLK	Exemption is limited to test systems intended for employment and insurance testing that include a statement in their labeling that the device is intended solely for use in employment and insurance testing, and does not include test systems intended for Federal drug testing programs (*e.g.,* programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.)
866.5750	System, Test, Radioallergosorbent (RAST) Immunological.	PUW	DHB	Exemption is limited to devices classified under 21 CFR 866.5750 that are intended to detect any of the allergens included in table 3 of this document.
868.2385	Analyzer, Nitrogen Dioxide	PUG	MRQ	Exemption is limited to standalone nitrogen dioxide analyzers and not those that are components of nitric oxide delivery systems intended to monitor nitrogen dioxide levels during inhaled nitric oxide therapy.
870.1330	Wire, Guide, Catheter	PTL	DQX	Exemption is limited to accessory torque devices that are manually operated, non-patient contacting, and intended to manipulate non-cerebral vascular guide wires.
870.1650	Syringe, Balloon Inflation	PTM	MAV	Exemption is limited to non-patient contacting balloon inflation syringes intended only to inflate/deflate balloon catheters and monitor pressure within the balloon.
870.2770	Analyzer, Body Composition	PUH	MNW	Exemption is limited to body composition analyzers which are not intended to diagnose or treat any medical condition.
870.4400	Reservoir, Blood, Cardiopulmonary Bypass.	PTN	DTN	Exemption is limited to cardiopulmonary bypass blood reservoirs that do not contain defoamers or blood filters.
874.1090	Tester, Auditory Impedance	PTO	ETY	Exemption is limited to auditory impedance testers that are in compliance with FDA-recognized consensus standard ANSI S3.39.
874.1090	Tympanometer	PTP	NAS	Exemption is limited to tympanometers that are in compliance with FDA-recognized consensus standard ANSI S3.39.
876.1500	Endoscopic Magnetic Retriever.	PTQ	FCC	Exemption is limited to endoscopic magnetic retrievers intended for single use.
876.1500	Scissors For Cystoscope	PTR	KGD	Exemption is limited to sterile scissors for cystoscope intended for single use.

TABLE 2—CLASS II DEVICES—Continued

21 CFR Section	Device type	Exempt product code	Former product code (non-exempt)	Partial exemption limitation
876.1500	Endoscopic Grasping/Cutting Instrument, Non-Powered.	PTS	OCZ	Exemption is limited to disposable, non-powered endoscopic grasping/cutting instruments intended for single use.
876.5010	Catheter, Biliary, Surgical	PTT	GCA	Exemption is limited to surgical biliary catheters that do not include a balloon component.
876.5630	Catheter, Peritoneal, Long-Term Indwelling.	PTU	FJS	Exemption is limited to non-patient contacting catheter finger grips intended for single use.
876.5630	Catheter, Peritoneal Dialysis, Single Use.	PTV	FKO	Exemption is limited to non-patient contacting catheter finger grips intended for single use.
876.5630	System, Peritoneal, Automatic Delivery.	PTW	FKX	Exemption is limited to continuous ambulatory peritoneal dialysis (CAPD) belts and catheter stands that do not include weigh scales.
878.4370	Drape, Surgical	PUI	KKX	Exemption is limited to surgical drapes that do not include an antimicrobial agent.
878.4495	Suture, Nonabsorbable, Steel, Monofilament And Multifilament, Sterile.	PTX	GAQ	Exemption is limited to steel monofilament sutures that are uncoated and do not incorporate barbs.
882.1470	Computerized Cognitive Assessment Aid.	PTY	PKQ	Exemption is limited to computerized cognitive assessment aids that are not intended for diagnostic assessment of specific diseases or conditions and rely on inputs from visual cues, auditory cues, and/or functional use of the hand.
884.1630	Colposcope (and Colpomicroscope).	PTZ	HEX	Exemption is limited to standard colposcopes (and colpomicroscopes) that use only a white light source, do not use filters other than a green filter, do not include image analysis software, and are not smartphone-based.
884.4530	Tenaculum, Uterine	PUA	HDC	Exemption is limited to sterile uterine tenaculum devices that do not use suction and are intended for single use.
884.6120	Accessory, Assisted Reproduction.	PUB	MQG	Exemption is limited to simple embryo incubators with temperature, gas, and humidity control only; syringe pumps; collection tube warmers; dish/plate/microscope stage warmers; and controlled-rate cryopreservation freezers.
884.6130	Microtools, Assisted Reproduction (Pipettes).	PUC	MQH	Exemption is limited to assisted reproduction microtools (pipettes) manufactured from glass.
884.6160	Labware, Assisted Reproduction.	PUD	MQK	Exemption is limited to dishes and plates that are intended for general assisted reproduction technology procedures.
886.1850	Biomicroscope, Slit-Lamp, AC-Powered.	PUE	HJO	Exemption is limited to slit-lamp, AC-powered biomicroscopes intended only for the visual examination of the anterior segment of the eye, are classified as Group 1 per FDA-recognized consensus standard ANSI Z80.36, do not provide any quantitative output, and are not intended for screening or automated diagnostic indications.
886.3320	Ocular Peg	PUF	MQU	Exemption is limited to ocular pegs supplied sterile.

In table 2, FDA included devices classified under § 866.5750 (Radioallergosorbent (RAST) immunological test system). FDA does not believe that all devices classified under this regulation meet the exemption criteria from premarket notification requirements. The devices listed in table 3 are also classified under § 866.5750, but this subset no longer requires premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in § 866.9. While the non-exempt devices classified under § 866.5750 will retain product code ''DHB'', these devices listed in table 3 are reassigned product code ''PUW.''

TABLE 3—CLASS II DEVICES

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
	Grass Pollens	
g1	Sweet vernal grass	*Anthoxanthum odoratum.*
g3	Cocksfoot grass, Orchard grass	*Dactylis glomerata.*
g4	Meadow fescue	*Festuca elatior.*
g5	Rye-grass (perennial rye grass)	*Lolium perenne.*
g7	Common reed (common reed grass)	*Phragmites communis.*
g8	Meadow grass, Kentucky blue (June grass)	*Poa pratensis.*

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
g9	Redtop, Bentgrass	*Agrostis stolonifera* *Agrostis gigantea* (*Agrostis alba*).
g11	Brome grass	*Bromus inermis.*
g12	Cultivated rye (cultivated rye grass)	*Secale cereale.*
g13	Velvet grass	*Holcus lanatus.*
g14	Cultivated oat (cultivated oat grass)	*Avena sativa.*
g15	Cultivated wheat (cultivated wheat grass)	*Triticum aestivum* (*Triticum* spp.).
g16	Meadow foxtail (meadow foxtail grass)	*Alopecurus pratensis.*
g17	Bahia grass	*Paspalum notatum.*
g24	Wheat grass, Western	*Agropyron smithii* (*Elymus smithii*).
g30	Bluegrass, annual	*Poa annua.*
g70	Wild rye grass	*Elymus triticoides* *Elymus condensatus.*
g71	Canary grass	*Phalaris arundinacea.*
g201	Barley, cultivated	*Hordeum vulgare.*
g202	Maize, corn (cultivated corn)	*Zea mays.*
g203	Salt grass	*Distichlis spicata.*
g204	False oat-grass	*Arrhenatherum elatius.*
g216	Cyn d 1	*Cynodon dactylon.*
g701	Phl p 1.0102, Phl p 5.0101	*Phleum pratense.*
g702	Phl p 7.0101	*Phleum pratense.*
g703	Phl p 12.0101	*Phleum pratense.*
	Weed Pollens	
w2	Western ragweed	*Ambrosia psilostachya.*
w4	False ragweed	*Ambrosia acanthicarpa* (*Franseria acanthicarpa*).
w5	Wormwood	*Artemisia absinthium* *Artemisia annua.*
w6	Mugwort	*Artemisia vulgaris.*
w7	Marguerite, ox-eye daisy	*Chrysanthemum leucanthemum.*
w8	Dandelion	*Taraxacum vulgare* *Taraxacum officinale.*
w9	Plantain (English), Ribwort	*Plantago lanceolata.*
w10	Goosefoot, lamb's quarters	*Chenopodium album.*
w11	Saltwort (prickly), Russian thistle	*Salsola kali* (*Salsola pestifer*).
w12	Goldenrod	*Solidago virgaurea* (*Solidago* spp.)
w13	Cocklebur, common	*Xanthium commune.*
w14	Common pigweed (rough pigweed)	*Amaranthus retroflexus.*
w15	Scale, Lenscale	*Atriplex lentiformis.*
w16	Rough marsh elder	*Iva ciliate* *Iva annua.*
w17	Firebush (Kochia)	*Kochia scoparia.*
w18	Sheep sorrel	*Rumex acetosella.*
w19	Wall pellitory	*Parietaria officinalis.*
w20	Nettle (Common stinging nettle)	*Urtica dioica.*
w21	Wall pellitory	*Parietaria judaica.*
w22	Japanese hop (careless weed)	*Humulus japonicas* (*Humulus scandens*).
w23	Yellow dock, Yellow dockweed	*Rumex crispus.*
w24	Spiny pigweed	*Amaranthus spinosus.*
w27	Carnation	*Dianthus* spp.
w28	Rose	*Rosa rugosa.*
w33	Clover	*Trifolium pratense.*
w35	Mexican tea	*Chenopodium ambrosioides.*
w36	Rabbit bush	*Ambrosia deltoidea* (*Franseria deltoides*).
w37	Salt bush, annual	*Atriplex wrightii.*
w39	Water hemp, Western	*Amaranthus rudis* (*Acnida tamariscina*).
w41	Burrobrush	*Hymenoclea salsola.*
w42	Poverty weed.	
w43	Common sagebrush	*Artemisia tridentata.*
w45	Alfalfa	*Medicago sativa.*
w46	Dog fennel	*Eupatorium capillifolium.*

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
w53	Geranium	*Geranium* spp.
w67	Groundsel bush	*Baccharis halimifolia.*
w69	Iodine bush	*Allenrolfea occidentalis.*
w70	Ragweed, slender	*Ambrosia confertiflora.*
w75	Wing scale (wingscale)	*Atriplex canescens.*
w82	Careless weed	*Amaranthus palmeri* *Amaranthus hybridus.*
w90	Japanese hop	*Humulus japonicas* (*Humulus scandens*).
w203	Rape (rape pollen)	*Brassica napus.*
w204	Sunflower	*Helianthus annuus.*
w206	Camomile	*Matricaria chamomilla.*
w207	Lupin	*Lupinus* spp.
w210	Sugar-beet	*Beta vulgaris.*
w211	Par j 2.0101	*Parietaria judaica.*
w231	Art v 1	*Artemisia vulgaris* (Mugwort).
w232	Sal k 1	*Salsola kali.*
w233	Art v 3	*Artemisa vulgaris* (LTP, Mugwort).
w234	Pla l 1	*Plantago lanceolata.*
w235	Che a 1.0101	*Chenopodium album.*
w236	Mer a 1.0101	*Mercurialis annua.*
a753	Art v 1	*Artemisia vulgaris* (Mugwort weed).
	Tree Pollens	
t1	Box-elder (Maple)	*Acer negundo.* *Acer saccharum.*
t2	Gray alder, speckled alder (alder)	*Alnus incana.*
t4	Hazel, hazelnut	*Corylus avellana.* *Corylus americana.*
t5	American beech (beech)	*Fagus grandifolia.* (*Fagus americana*).
t6	Mountain juniper, Mountain cedar	*Juniperus ashei* (*Juniperus sabinoides*).
t8	Elm	*Ulmus americana.*
t9	Olive	*Olea europaea.*
t10	Walnut	*Juglans californica* *Juglans nigra.*
t11	Maple leaf sycamore, London plane, Plane tree	*Platanus acerifolia.*
t61	Sycamore	*Platanus occidentalis.*
t12	Willow	*Salix caprea* *Salix nigra.*
t14	Cottonwood (Eastern Cottonwood/Black Cottonwood)	*Populus deltoides.*
t15	White ash	*Fraxinus americana.*
t16	White pine	*Pinus strobus.*
t18	Eucalyptus, gum-tree	*Eucalyptus globulus.* (*Eucalyptus* spp.).
t19/t26	Acacia	*Acacia longifolia* (*Acacia* spp.).
t20	Mesquite	*Prosopis glandulosa/* *Prosopis juliflora.*
t21	Melaleuca, cajeput tree	*Melaleuca quinquenervia* (*Melaleuca leucadendron*).
t22	Pecan, hickory	*Carya illinoinensis* (*Carya pecan*).
t23	Italian/Mediterranean/funeral cypress	*Cupressus sempervirens.*
t24	Japanese cypress	*Chamaecyparis obtusa* (*Chamaecyparis* spp.).
t25	Ash	*Fraxinus excelsior.*
t27	Maple, red	*Acer rubrum.*
t29	Acacia	*Acacia* spp.
t30	Birch, white	*Betula populifolia.*
t32	Willow, black	*Salix nigra.*
t33	Ash, Arizona	*Fraxinus velutina.*
t35	Cedar, salt	*Tamarix gallica.*
t37	Bald cypress (white bald cypress)	*Taxodium distichum.*
t38	Elm, Chinese/Siberian	*Ulmus pumila.*
t40	Hazelnut tree	*Corylus americana.*
t41	White hickory	*Carya alba* (*Carya tomentosa*).
t42	Oak, red	*Quercus rubra.*
t43	Loblolly pine	*Pinus taeda.*
t44	Hackberry	*Celtis occidentalis.*

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
t45	Cedar elm	*Ulmus crassifolia.*
t47	Juniper, one seed	*Juniperus monosperma.*
t48	Pine, lodgepole	*Pinus contorta.*
t49	Pine, ponderosa	*Pinus ponderosa.*
t50	Beech, European	*Fagus sylvatica.*
t51	Tree of Heaven	*Ailanthus altissima.*
t52	Western white pine	*Pinus monticola.*
t54	Russian olive	*Elaeagnus angustifolia.*
t55	Scotch broom	*Cytisus scoparius.*
t56	Bayberry	*Myrica cerifera.*
t57	Red cedar	*Juniperus virginiana.*
t60	Western juniper	*Juniperus occidentalis.*
t61	Sycamore	*Platanus occidentalis.*
t70	Mulberry (white mulberry)	*Morus alba.*
t71	Red mulberry	*Morus rubra.*
t72	Queen palm	*Arecastrum romanzoffiamon.*
t73	Australian pine	*Casuarina equisetifolia.*
t77	Oak mix (red, white, black)	*Quercus* spp.
t80	Japanese cypress	*Chamaecyparis obtusa.*
t81	Japanese alder	*Alnus japonica.*
t83	Mango tree	*Mangifera indica.*
t90	Walnut, black	*Juglans nigra.*
t96	Poplar, white (poplar)	*Populus alba.*
t103/ t218	Virginia live oak (live oak)	*Quercus virginiana.*
t105	Pepper tree	*Schinus molle.*
t110	Orange tree	*Citrus sinensis.*
t201	Spruce, Norway spruce	*Picea abies* (*Picea excelsa*).
t202	Alder, smooth	*Alnus incana* spp. *Rugosa* (*Alnus rugosa*).
t203	Horse chestnut	*Aesculus hippocastanum.*
t205	Elder	*Sambucus nigra.*
t206	Chestnut	*Castanea sativa.*
t207	Douglas fir	*Pseudotsuga menziesii* (*Pseudotsuga taxifolia*).
t208	Linden	*Tilia cordata.*
t209	Horn beam	*Carpinus betulus.*
t210	Privet	*Ligustrum vulgare.*
t211	Sweet gum	*Liquidambar styraciflua.*
t212	Cedar	*Libocedrus decurrens.*
t213	Pine	*Pinus radiata.*
t214	Date palm	*Phoenix canariensis.*
t215	Lilac	*Syringa vulgaris.*
t217	Pepper tree	*Schinus molle.*
t217	Red alder	*Alnus rubra.*
t218	Virginia live oak	*Quercus virginiana.*
t218	Bayberry (bayberry/sweet gale)	*Myrica gale.*
t219	Palo verde	*Cercidium floridum.*
t219	Red cedar	*Juniperus virginiana.*
t220	Bet v 4	*Betula verrucosa* (Birch).
t221	Bet v 2.0101, Bet v 4	*Betula verrucosa* (Birch).
t222	Cypress (Arizona cypress)	*Cupressus arizonica.*
t223	Oil palm	*Elaeis guineensis.*
t224	Ole e 1	*Olea europaea.*
t225	Bet v 6	*Betula verrucosa* (Birch).
t226	Cup a 1	*Cupressus arizonica.*
t227	Ole e 7	*Olea Europaea.*
t228	Aspen, quaking	*Populus tremuloides.*
t229	Eastern hemlock	*Tsuga canadensis.*
t230	Redwood (sequoia)	*Sequoia sempervirens.*
t232	Pussy willow	*Salix discolor.*
t240	Ole e 9.0101	*Olea Europaea.*
t241	Pla a 1.0101	*Platanus acerifolia.*
t242	Pla a 2	*Platanus acerifolia.*
t243	Pla a 3.0101	*Platanus acerifolia.*
t244	Cor a 1.0103	*Corylus avellana.*
t245	Aln g 1.0101	*Alnus glutinosa.*
t246	Cry j 1	*Cryptomeria japonica.*
t280	Locust tree	*Robinia pseudoacacia.*
t401	Brazilian peppertree	*Schinus terebinthifolius.*
t402	Mastic tree	*Pistacia lentiscus.*

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
t404	Tree of heaven	*Ailanthus altissima.*
t406	Date palm	*Phoenix dactylifera.*
a482	Ole e 1	*Olea europaea* (Olive Oil).
	Mites	
d207	Blo t 5.0101	*Blomia tropicalis.*
d208	Lep d 2.0101	*Lepidoglyphus destructor.*
	Microorganisms, Molds, Yeast	
m1	*Penicillium chrysogenum* (*Penicillium notatum*)	*Penicillium chrysogenum* (*Penicillium notatum*).
m2	*Cladosporium herbarum* (*Hormodendrum*)	*Cladosporium herbarum* (*Hormodendrum*).
m3	*Aspergillus fumigatus*	*Aspergillus fumigatus.*
m4	*Mucor racemosus*	*Mucor racemosus.*
m5	*Candida albicans*	*Candida albicans.*
m7	*Botrytis cinerea*	*Botrytis cinerea.*
m8	*Drechslera halodes* (*Setomelanomma rostrata, Helminthosporium halodes, Helminthosporium interseminatum*).	*Drechslera halodes* (*Setomelanomma rostrata, Helminthosporium halodes*).
m9	*Fusarium moniliforme* (*Fusarium proliferatum*)	*Fusarium moniliforme* (*Fusarium proliferatum*).
m10	*Stemphylium botryosum*	*Stemphylium herbarum* (*Stemphylium botryosum*).
m11	*Rhizopus nigricans*	*Rhizopus nigricans.*
m12	*Aureobasidium pullulans*	*Aureobasidium pullulans.*
m13	*Phoma betae*	*Phoma betae.*
m14	*Epicoccum purpurascens*	*Epicoccum purpurascens* (*Epicoccum nigrum*).
m15	*Trichoderma viride*	*Trichoderma viride.*
m16	*Curvularia lunata*	*Curvularia lunata* *Curvularia specifera* (K923044).
m17	*Cladosporium fulvum*	*Cladosporium fulvum.*
m18	*Fusarium culmorum*	*Fusarium culmorum.*
m19	*Aspergillus versicolor*	*Aspergillus versicolor.*
m20	*Mucor mucedo*	*Mucor mucedo.*
m21	*Aspergillus clavatus*	*Aspergillus clavatus.*
m22	*Micropolyspora faeni*	*Saccharopolyspora rectivirgula* (*Micropolyspora faeni*).
m23	*Thermoactinomyces vulgaris*	*Thermoactinomyces vulgaris.*
m24	*Stachybotrys atra*	*Stachybotrys chartarum* (*Stachybotrys atra*).
m24	*Paecilomyces* spp.	*Paecilomyces* spp.
m25	*Aspergillus versicolor*	*Aspergillus versicolor.*
m25	*Penicillium brevicompactum*	*Penicillium brevicompactum.*
m26	*Cladosporium cladosporioides*	*Cladosporium cladosporioides.*
m26	*Penicillium citrinum*	*Penicillium citrinum.*
m27	*Penicillium* spp.	*Penicillium* spp.
m29	*Aspergillus repens*	*Aspergillus repens.*
m30	*Penicillium roqueforti*	*Penicillium roqueforti.*
m32	*Cladosporium cladosporioides*	*Cladosporium cladosporioides.*
m34	*Serpula lacrymans*	*Serpula lacrymans.*
m36	*Aspergillus terreus*	*Aspergillus terreus.*
m37	*Trichophyton mentagrophytes*	*Trichophyton mentagrophytes.*
m40	*Aspergillus amstelodami*	*Aspergillus amstelodami.*
m43	*Saccharomyces carlsberg*	*Saccharomyces carlsbergensis.*
m44	*Saccharomyces cerevisiae*	*Saccharomyces cerevisiae.*
m45	*Hormodendrum hordei*	*Hormodendrum hordei.*
m46	*Bipolaris spicifera*	*Bipolaris spicifera.*
m47	*Aspergillus nidulans*	*Aspergillus nidulans.*
m48	*Aspergillus oryzae*	*Aspergillus oryzae.*
m49	*Fusarium oxysporum*	*Fusarium oxysporum.*
m50	*Micropolyspora faeni*	*Saccharopolyspora rectivirgula* (*Micropolyspora faeni*).
m51	*Thermoactinomyces vulgaris*	*Thermoactinomyces vulgaris.*
m53	*Microspora canis*	*Microsporum canis* (*Microspora canis*).
m54	*Aspergillus flavus*	*Aspergillus flavus.*
m63	*Helminthosporium intersemin*	*Helminthosporium intersemin.*
m66	*Mucor plumbeus*	*Mucor plumbeus.*
m67	*Mycogone*	*Mycogone perniciosa.*
m68	*Nigrospora oryzae*	*Nigrospora oryzae.*

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
m69	*Rhodotorula*	*Rhodotorula rubra* (*Rhodotorula mucilaginosa*).
m70	*Malassezia furfur* (*Pityrosporum orbiculare*)	*Malassezia furfur* (*Pityrosporum orbiculare*).
m71	*Spondylocladium*	*Spondylocladium* spp.
m72	*Epidermophyton*	*Epidermophyton floccosum*.
m73	*Epicoccum nigrum*	*Epicoccum purpurascens* (*Epicoccum nigrum*).
m80	*Staphylococcal enterotoxin A* (*Sta a SEA*)	*Staphylococcus aureus*.
m80	*Helminthosporium* spp.	*Helminthosporium* spp.
m81	*Staphylococcal enterotoxin B* (*Sta a SEB*)	*Staphylococcus aureus*.
m88	*Stemphylium solani*	*Stemphylium solani*.
m93	*Gliocladium fimbriatum*	*Gliocladium fimbriatum*.
m94	*Phycomyces blakesleeanus*	*Phycomyces blakesleeanus*.
m201	*Tilletia tritici* (*Ustilago nuda, Ustilago tritici*) (Barley smut)	*Tilletia tritici* (*Ustilago nuda, Ustilago tritici*).
m202	*Acremonium kiliense* (*Cephalosporium acremonium*)	*Acremonium kiliense* (*Cephalosporium acremonium*).
m203	*Trichosporon pullulans*	*Trichosporon pullulans*.
m204	*Ulocladium chartarum*	*Ulocladium chartarum*.
m205	*Trichophyton rubrum*	*Trichophyton rubrum*.
m207	*Aspergillus niger*	*Aspergillus niger*.
m208	*Chaetomium globosum*	*Chaetomium globosum*.
m209	*Penicillium frequentans*	*Penicillium glabrum* (*Penicillium frequentans*).
m209	*Stachybotrys chartarum*	*Stachybotrys chartarum* (*Stachybotrys atra*).
m210	*Trichophyton mentagrophytes var. goetzii*	*Trichophyton mentagrophytes var. goetzii*.
m211	*Trichophyton mentagrophytes var. interdigitale*	*Trichophyton mentagrophytes var. interdigitale*.
m211	Oat smut	*Ustilago avenae*.
m212	*Micropolyspora faeni*	*Saccharopolyspora rectivirgula* (*Micropolyspora faeni*).
m212	*Geotrichum candidum*	*Geotrichum candidum*.
m213	Bermuda grass smut	*Ustilago cynodontis*.
m214	Johnson grass smut	*Sphacelotheca cruenta*.
m215	Corn smut	*Ustilago maydis*.
m218	Asp f 1.0101	*Aspergillus fumigatus*.
a3050	Asp r 1	*Aspergillus restrictus*.
m219	Asp f 2	*Aspergillus fumigatus*.
m220	Asp f 3.0101	*Aspergillus fumigatus*.
m221	Asp f 4	*Aspergillus fumigatus*.
m222	Asp f 6.0101	*Aspergillus fumigatus*.
m223	*Staphylococal enterotoxin C* (*Sta a SEC*)	*Staphylococus aureus*.
m224	*Staphylococcal enterotoxin D* (*Sta a SED*)	*Staphylococcus aureus*.
m226	*Staphylococcal enterotoxin TSST* (*Sta a TSST*)	*Staphylococcus aureus*.
m227	*Malassezia* spp. (*Pityrosporum* spp.)	*Malassezia* spp. (*Pityrosporum* spp.).
m228	*Aspergillus flavus*..	
m229	Alt a 1.0101	*Alternaria alternata* (*Alternaria tenuis*).
m230	Alt a 6.0101	*Alternaria alternata* (*Alternaria tenuis*).
m231	Cla h 8.0101	*Cladosporium herbarum* (*Hormodendrum*).
m300	*Eurotium* spp.	*Eurotium* spp.
m304	*Aspergillus oryzae*	*Aspergillus oryzae*.
m305	*Penicillium brevicompactum*	*Penicillium brevicompactum*.
m309	*Aspergillus terreus*	*Aspergillus terreus*.
m310	*Aspergillus nidulans*	*Aspergillus nidulans*.
m311	*Aspergillus flavus*	*Aspergillus flavus*.
m312	*Aspergillus clavatus*	*Aspergillus clavatus*.
	Epidermal & Animal	
e6	Guinea pig epithelium	*Cavia porcellus*.
e7	Pigeon droppings	*Columba palumbus* *Columba livia*.
e25	Chicken serum	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e26	Parrot serum	*Psittacoidea* spp.
e62	Camel	*Camelus dromedaries*.
e70	Goose feathers	*Anser anser*.
e71	Mouse epithelium	*Mus musculus* (*Mus* spp.).
e73	Rat epithelium	*Rattus norvegicus*.
e74	Rat urine proteins	*Rattus norvegicus* *Rattus rattus*.

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
e75	Rat serum proteins	*Rattus norvegicus* *Rattus rattus*.
e76	Mouse serum proteins	*Mus musculus* (*Mus* spp.).
e77	Budgerigar droppings	*Melopsittacus undulatus*.
e78	Budgerigar feathers	*Melopsittacus undulatus*.
e79	Budgerigar serum proteins	*Melopsittacus undulatus*.
e80	Goat epithelium	*Capra hircus*.
e81	Sheep epithelium	*Ovis aries* (*Ovis* spp.).
e82	Rabbit epithelium	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
e83	Swine epithelium	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
e84	Hamster epithelium	*Cricetus cricetus, Mesocricetus auratus, and Phodopus sungorus*.
e85	Chicken feathers	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e86	Duck feathers	*Anas platyrhynchos*.
e87	Rat epithelium, serum proteins, and urine proteins	*Rattus norvegicus* *Rattus rattus*.
e88	Mouse epithelium, serum proteins, and urine proteins (mouse)	*Mus musculus* (*Mus* spp.).
e89	Turkey feathers	*Meleagris gallopavo*.
e90	Budgerigar serum proteins, feathers, and droppings	*Melopsittacus undulatus*.
e91	Pigeon serum proteins, feathers, and droppings	*Streptopelia roseogrisea* *Psittacidae* spp.
e92	Parrot serum proteins, feathers, and droppings	*Ara* spp.
e93	Pigeon serum proteins	*Streptopelia roseogrisea*.
e94	Fel d 1.0101	*Felis domesticus*.
a345	Fel d 1	*Felis domesticus*.
e98	Parrot droppings	*Psittacoidea* spp.
e101	Can f 1.0101	*Canis familiaris* (*Canis domesticus*).
a174	Can f 1	*Canis familiaris* (*Canis domesticus*).
e102	Can f 2.0101	*Canis familiaris* (*Canis domesticus*).
e196	Parakeet feathers	*Nymphicus hollandicus*.
e197	Parakeet droppings	*Nymphicus hollandicus*.
e198	Parakeet serum	*Nymphicus hollandicus*.
e199	Canary bird serum	*Serinus canarius*.
e200	Canary bird droppings	*Serinus canarius*.
e201	Canary bird feathers (Canary feathers)	*Serinus canarius*.
e202	Reindeer epithelium	*Rangifer tarandus*.
e203	Mink epithelium	*Mustela* spp.
e204	Bos d 6	*Bos domesticus* (*Bos taurus; Bos* spp.).
e205	Horse, serum proteins	*Equus caballus* (*Equus* spp.).
e206	Rabbit, serum proteins	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
e208	Chinchilla epithelium	*Chinchilla laniger*.
e209	Gerbil epithelium	*Meriones unguiculatus*.
e210	Fox epithelium	*Vulpes vulpes*.
e211	Rabbit, urine proteins	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
e212	Swine, urine proteins	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
e213	Parrot feathers	*Ara* spp.
e214	Finch feathers	*Lonchura domestica*.
e215	Pigeon feathers	*Streptopelia roseogrisea* (*Streptopelia* spp.) *Columbia* spp.
e216	Deer epithelium	*Dama dama*.
e217	Ferret epithelium	*Mustela putorius*.
e218	Chicken droppings	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e219	Chicken, serum proteins	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
e220	Fel d 2, Cat serum albumin	*Felis domesticus*.
e221	Can f 3	*Canis familiaris* (*Canis domesticus*) (Dog serum albumin).
e222	Swine serum albumin (Sus s PSA)	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
e225	Lovebird feathers	*Psittacoidea agapomis*.
e226	Can f 5.0101	*Canis familiaris*.
e227	Equ c 1.0101	*Equus caballus*.
e228	Fel d 4.0101	*Felis domesticus*.
e230	Equ c 3	*Equus caballus*.

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
e231	Mus m 1	*Mus musculus*.
	Food	
f9	Rice	*Oryza sativa*.
f12	Pea (green pea)	*Pisum sativum*.
f15	White bean	*Phaseolus vulgaris*.
f19	Cayenne pepper	*Capsicum frutescens* (*Capsicum annum*).
f21	Sugar cane	*Saccharum officinarum*.
f22	Raspberry	*Rubus idaeus*.
f26	Pork	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
f29	Watermelon	*Citrullus lanatus* (*Citrullus vulgaris*).
f31	Carrot	*Daucus carota*.
f32	Oyster mushroom	*Pleurotus ostreatus*.
f33	Orange	*Citrus sinensis*.
f35	Potato	*Solanum tuberosum*.
f43	Mother's milk	*Homo sapiens*.
f44	Strawberry	*Fragaria vesca* (*Fragaria* spp.).
f45	Yeast, baker's	*Saccharomyces cerevisiae*.
f46	Pepper, Red	*Capsicum annuum*.
f47	Garlic	*Allium sativum*.
f48	Onion	*Allium cepa*.
f49	Apple	*Malus x domestica* (*Malus* spp.).
f51	Bamboo shoot	*Phyllostachys pubescens*.
f52	Cacao/chocolate	*Theobroma cacao*.
f54	Sweet potato	*Ipomoea batatas*.
f55	Common millet	*Panicum miliaceum*.
f56	Foxtail millet	*Setaria italica*.
f57	Japanese millet	*Echinochloa crus-galli*.
f58	Pacific squid	*Todarodes pacificus*.
f59	Octopus	*Octopus vulgaris* (*Octopus* spp.).
f63	Kefir	NA.
f67	Parmesan cheese	NA.
f81	Cheese, cheddar type	NA.
f82	Cheese, mold type	NA.
f83	Chicken	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
f86	Parsley	*Petroselinum crispum*.
f87	Melon	*Cucumis melo Cucumis melo + Citrullus lanatus*.
f88	Mutton (lamb)	*Ovis aries* (*Ovis* spp.).
f90	Malt	*Hordeum vulgare*.
f92	Banana	*Musa* spp.
f93	Cacao	*Theobroma cacao*.
f94	Pear	*Pyrus communis* (*Pyrus* spp.).
f97	Yam	*Dioscorea* spp. *Dioscorea opposita*.
f97	Chamomile tea	*Matricaria chamomilla*.
f98	Gliadin	*Triticum aestivum* (*Triticum* spp.).
f102	Cantaloupe	*Cucumis melo var. cantalupensis*.
f105	Chocolate	*Theobroma cacao*.
f109	Cottonseed	*Gossypium hirsutum*.
f110	Giant radish	*Raphanus sativus*.
f118	Zucchini	*Cucurbita pepo*.
f119	Radish	*Raphanus sativus*.
f120	Venison	*Capreolus capeolus*.
f121	Pinto bean	*Phaseolus vulgaris*.
f122	Cheese, American	NA.
f127	Black-eyed pea	*Vigna unguiculata*.
f131	Black Olive	*Olea europaea*.
f136	Red beet	*Beta vulgaris var. conditiva*.
f139	Goat's Cheese	*Capra aegagrus*.
f140	Bran	NA.
f141	Corn (vegetables)	*Zea mays*.
f152	Green bell pepper	*Capsicum annuum*.
f155	Brewer's yeast	*Saccharomyces carlsbergensis*.
f157	Duck	*Anas domesticus*.
f158	Goose	*Anser anser*.
f160	Camembert cheese	NA.

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
f162	Nectarine	*Prunus persica var. nucipersica*.
f163	Kohlrabi	*Brassica oleracea var. gongylodes*.
f65	Perch.	
f166	Leek	*Allium porrum*.
f170	Cheese (Switzerland) (Swiss cheese)	NA.
f174	Fig	*Ficus carica*.
f177	Cranberry	*Vaccinium macrocarpon*.
f179	Raisin	*Vitis* spp.
f182	Lima bean	*Phaseolus lunatus*.
f198	Flaxseed (bruised grain)	*Linum usitatissimum*.
f199	Untreated native milk	*Bos domesticus* (*Bos taurus; Bos* spp.).
f208	Lemon	*Citrus limon*.
f209	Grapefruit	*Citrus paradisi*.
f210	Pineapple	*Ananas comosus*.
f211	Blackberry	*Rubus fruticosus*.
f212	Mushroom (champignon)	*Agaricus hortensis* (*Agaricus* spp.).
f213	Rabbit	*Oryctolagus cuniculus* (*Oryctolagus* spp.).
f214	Spinach	*Spinacia oleracea*.
f215	Lettuce	*Lactuca sativa*.
f216	Cabbage	*Brassica oleracea var. capitata*.
f217	Brussels sprouts	*Brassica oleracea var. gem*.
f218	Paprika, sweet pepper	*Capsicum annuum*.
f219	Fennel seed	*Foeniculum vulgare*.
f219	Sage	*Salvia officinalis*.
f220	Cinnamon	*Cinnamomum* spp.
f221	Coffee	*Coffea* spp.
f222	Tea	*Camellia sinensis*.
f223	Green olive	*Olea europaea*.
f225	Summer squash, pumpkin	*Cucurbita pepo*.
f225	Pumpkin	*Cucurbita maxima*.
f226	Pumpkin seed	*Cucurbita pepo*.
f227	Sugar-beet seed	*Beta vulgaris*.
f229	Safflower Seed	*Carthamus tinctorius*.
f231	Milk, boiled	*Bos domesticus* (*Bos taurus; Bos* spp.).
f234	Vanilla	*Vanilla planifolia*.
f237	Apricot	*Prunus armeniaca*.
f241	Gouda cheese	NA.
f242	Cherry	*Prunus avium*.
f244	Cucumber	*Cucumis sativus*.
f246	Guar, guar gum	*Cyamopsis tetragonoloba*.
f247	Honey	NA.
f248	Rosemary	*Rosmarinus officinalis*.
f254	Plaice	*Pleuronectes platessa*.
f255	Plum	*Prunus domestica* *Prunus americana*.
f258	Squid	*Loligo* spp.
f259	Grape	*Vitis vinifera* (*Vitis* spp.).
f260	Broccoli	*Brassica oleracea var. italica* (*Brassica oleracea var. cultivar*).
f261	Asparagus	*Asparagus officinalis*.
f262	Aubergine, eggplant	*Solanum melongena*.
f263	Green pepper	*Piper nigrum* *Capsicum annuum*.
f264	Eel	*Anguilla anguilla*.
f265	Caraway	*Carum carvi*.
f265	Cumin	*Cuminum cyminum*.
f266	Mace	*Myristica fragrans*.
f267	Cardamon	*Elettaria cardamomum*.
f268	Clove	*Syzygium aromaticum*.
f269	Basil	*Ocimum basilicum*.
f270	Ginger	*Zingiber officinale*.
f271	Anise	*Pimpinella anisum*.
f272	Tarragon	*Artemisia dracunculus*.
f273	Thyme	*Thymus vulgaris*.
f274	Marjoram	*Origanum majorana*.
f275	Lovage	*Levisticum officinale*.
f276	Fennel, fresh	*Foeniculum vulgare*.

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
f277	Dill	*Anethum graveolens*.
f278	Bay leaf	*Laurus nobilis*.
f279	Chili pepper	*Capsicum frutescens*.
f280	Black pepper	*Piper nigrum*.
f281	Curry (Santa Maria)	NA.
f282	Nutmeg	*Myristica fragrans*.
f283	Oregano	*Origanum vulgare*.
f284	Turkey meat	*Meleagris gallopavo*.
f285	Elk/moose meat	*Alces* spp.
f286	Mare's milk	*Equus caballus* (*Equus* spp.).
f287	Red kidney bean	*Phaseolus vulgaris*.
f288	Blueberry	*Vaccinium myrtillus* (*Vaccinium* spp.).
f289	Date	*Phoenix dactylifera*.
f291	Cauliflower	*Brassica oleracea var. botrytis*.
f292	Guava	*Psidium guajava*.
f293	Papaya	*Carica papaya*.
f294	Passion fruit, Maracuja	*Passiflora edulis* (*Passiflora* spp.).
f295	Carambola	*Averrhoa carambola*.
f296	Carob	*Ceratonia siliqua*.
f297	Gum arabic	*Acacia senegal* (*Acacia* spp.).
f298	Tragacanth	*Astragalus* spp.
f299	Sweet chestnut (chestnut)	*Castanea sativa*.
f300	Pinto bean	*Phaseolus* spp.
f301	Persimmon (kaki fruit, sharon)	*Diospyros kaki*.
f302	Mandarin (tangerine, clementine, satsumas)	*Citrus reticulata*.
f305	Fenugreek	*Trigonella foenum-graecum*.
f306	Lime	*Citrus aurantifolia*.
f307	Hake	*Merluccius merluccius*.
f308	Sardine (pilchard)	*Sardina pilchardus*.
f310	Blue vetch	*Lathyrus sativus*.
f311	Megrim	*Lepidorhombus whiffiagonis*.
f315	Green bean	*Phaseolus vulgaris*.
f316	Rape seed	*Brassica napus*.
f317	Coriander	*Coriandrum sativum*.
f318	Jack fruit	*Artocarpus heterophyllus*.
f319	Beetroot	*Beta vulgaris*.
f320	Crayfish	*Astacus astacus*.
f321	Horse meat	*Equus caballus* (*Equus* spp.).
f322	Red currant	*Ribes sylvestre*.
f324	Hop (fruit cone)	*Humulus lupulus*.
f325	Saffron	*Colchicum autumnale*.
f328	Fig	*Ficus carica*.
f329	Watermelon	*Citrullus lanatus*.
f330	Rose hip	*Rosa* spp.
f331	Saffron	*Crocus sativus*.
f332	Mint	*Mentha piperita*.
f333	Linseed	*Linum usitatissimum*.
f336	Jujube	*Ziziphus jujuba*.
f336	Wine vinegar	*Vitis vinifera* (*Vitis* spp.).
f337	Sole	*Solea solea*.
f337	English sole	*Parophrys vetulus*.
f338	Wine, white	*Vitis vinifera* (*Vitis* spp.).
f339	Allspice	*Pimenta dioica*.
f339	Wine, red	*Vitis vinifera* (*Vitis* spp.).
f341	Cranberry	*Vaccinium oxycoccus* *Vaccinium macrocarpon*.
f342	Olive (black, fresh)	*Olea europaea*.
f343	Raspberry	*Rubus idaeus*.
f344	Sage	*Salvia officinalis*.
f346	Chives	*Allium schoenoprasum*.
f347	Quinoa	*Chenopodium quinoa*.
f348	Litchi	*Litchi chinensis*.
f349	Chum salmon roe	*Oncorhynchus keta*.
f358	Artichoke	*Cynara scolymus*.
f360	Yogurt	NA.
f368	Black bass	*Micropterus dolomieu* (*Micropterus dolomieui*).
f374	Karaya gum	*Sterculia urens*.
f375	Horseradish	*Armoracia rusticana*.
f377	Maple syrup	NA.
f379	Okra	*Abelmoschus esculentus*.

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
f382	Beet, sugar	*Beta vulgaris var. altissima.*
f401	Loquat	*Eriobotrya japonica.*
f402	Fig	*Ficus carica.*
f403	Brewer's yeast	*Saccharomyces cerevisiae.*
f405	Mint	*Mentha* spp.
f406	Arugula	*Eruca vesicaria.*
	House Dust	
h1	Greer Labs., Inc.	NA.
h2	Hollister-Stier Labs.	NA.
h6	Japan	NA.
	Venoms & Insects	
i7	Midge	*Chironomus yoshimatsui.*
i8	Moth	*Bombyx mori* *Heterocera* spp.
i47	Water flea	*Daphnia* spp.
i49	Deer fly	*Chrysops* spp.
i51	Black ant	*Camponotus pennsylvanicus.*
i54	Flea mix (dog/cat), common flea	*Ctenocephalides* spp.
i71	Mosquito	*Aedes communis* *Aedes* spp. and *Culex* spp.
i72	Green nimitti	*Cladotanytarsus lewisi.*
i73	Blood worm	*Chironomus thummi* *Chironomusri parius* *Chironomus* spp.
i75	European hornet	*Vespa crabro.*
i76	Berlin beetle	*Trogoderma angustum.*
i77	European paper wasp	*Polistes dominulus.*
i78	Fly	*Musca domestica.*
i80	Bumblebee	*Bombus pennsylvanicus.*
i201	Horse bot fly	*Gasterophilus intestinalis.*
i202	Grain weevil	*Sitophilus granarius.*
i203	Mediterranean flour moth	*Ephestia kuehniella* (*Anagasta kuehniella*).
i204	Horse fly	*Tabanus* spp.
i205	Bumblebee	*Bombus terrestris.*
i208	Api m 1.0101	*Apis mellifera.*
a45	Api m 1	*Apis mellifera.*
i209	Ves v 5.0101	*Vespula vulgaris.*
a670	Ves v 5	*Vespula vulgaris.*
i210	Pol d 5.0101	*Polistes dominulus.*
i211	Ves v 1.0101	*Vespula vulgaris.*
i213	Api m 4	*Apis mellifera.*
i214	Api m 2	*Apis mellifera.*
i215	Api m 3	*Apis mellifera.*
i216	Api m 5	*Apis mellifera.*
i217	Api m 10	*Apis mellifera.*
i220	Bla g 1.0101	*Blattella germanica.*
i221	Bla g 2.0101	*Blattella germanica.*
i222	Bla g 5.0101	*Blattella germanica.*
i223	Bla g 7	*Blattella germanica*
a46	Api m 2	*Apis mellifera.*
	Miscellaneous	
o1	Cotton, crude fibers	*Gossypium* spp.
o3	Cotton (treated)	*Gossypium* spp.
o70	Seminal fluid	*Homo sapiens.*
o71	*Staphylococcus aureus*	*Staphylococcus aureus.*
o72	*Pichia pastoris* crude extract customer specific	*Pichia pastoris.*
o72	Sperm-sediment	*Homo sapiens.*
o73	*Pichia pastoris* crude extr. vector customer specific	*Pichia pastoris.*
o74	*Pichia pastoris* with vector customer specific	*Pichia pastoris.*
o201	Tobacco leaf, tobacco dust	*Nicotiana tabacum.*
o202	Artemia salina, fish feed	*Artemia salina.*
o203	Tetramin, fish feed	NA.
o207	Daphnia, fish feed	*Daphnia* spp.
o211	Mealworm	*Tenebrio molitor.*

TABLE 3—CLASS II DEVICES—Continued

[§ 866.5750—Radioallergosorbent (RAST) Immunological Test Systems]

Allergen code	Allergen product	Source (taxonomical name)
o212	Streptavidin	*Streptomyces avidini*.
o213	MBP (maltose binding protein)	*Escherichia coli*.
o214	CCD; MUXF3 from bromelain	*Ananas comosus*.
o72	Enterotoxin A (Sta a SEA)	*Staphylococcus aureus*.
o73	Enterotoxin B (Sta a SEB)	*Staphylococcus aureus*.
	Parasites	
p1	Ascaris	*Ascaris suum*.
p2	Echinococcus	*Echinococcus granulosus*.
p3	Schistosoma	*Schistosoma mansoni*.
p4	Anisakis (Herring Worm)	*Anisakis simplex* (*Anisakis* spp.).
p5	Toxocara canis	*Toxocara canis*.
p10	Ani s 3.0101	*Anisakis simplex* (*Anisakis* spp.).
p11	Ani s 1	*Anisakis simplex* (*Anisakis* spp.).
	Occupational	
k4	Threshing dust	NA.
k5	Flax	NA.
k7	Hay Dust	NA.
k8	Hop (hops)	*Humulus lupulus*.
k12	Grain mill dust	NA.
k14	Kapok	NA.
k20	Sheep's wool (treated) (wool)	*Ovis aries* (*Ovis* spp.).
k21	Sheep's wool (Untreated)	*Ovis aries* (*Ovis* spp.).
k23	Straw Dust	NA.
k33	Oak	NA.
k70	Green coffee bean	*Coffea* spp.
k71	Castor bean	*Ricinus communis*.
k72	Ispaghula	*Plantago psyllium/Plantago ovata*.
k73	Silk waste	NA.
k74	Silk	*Bombyx mori*.
k75	Isocyanate TDI (Toluene diisocyanate)	NA.
k76	Isocyanate MDI (Diphenylmethane diisocyanate)	NA.
k77	Isocyanate HDI (Hexamethylen diisocyanate)	NA.
k78	Ethylene oxide	NA.
k79	Phthalic anhydride	NA.
k80	Formaldehyde/Formalin	NA.
k81	Ficus	*Ficus benjamina* (*Ficus* spp.).
k83	Cotton seed	*Gossypium hirsutum*.
k84	Sunflower seed	*Helianthus annuus*.
k85	Chloramin T	NA.
k86	Trimellitic anhydride, TMA	NA.
k87	Asp o 21, alpha-amylase	*Aspergillus oryzae*.
k89	Orris root	*Iris florentina*.
k99	HSA (Human Serum Albumin) (Hom s HSA)	*Homo sapiens*.
k201	Car p 1, Papain	*Carica papaya*.
k202	Ana c 2, Bromelain	*Ananas comosus*.
k204	Maxatase	*Bacillus licheniformis*.
k205	Alcalase	*Bacillus* spp.
k206	Savinase, Protease 1 (Bac l Subtilisin)	*Bacillus* spp.
k208	Gal d 4, Lysozyme	*Gallus domesticus* (*Gallus gallus domesticus; Gallus* spp.).
k209	Hexahydrophtalic anhydrid	NA.
k210	Maleic anhydride	NA.
k211	Methyltetrahydrophtalic anhydrid	NA.
k212	Abachi wood dust	*Triplochiton scleroxylon*.
k213	Pepsin (Sus s Pepsin)	*Sus scrofa* (*Sus scrofa domesticus; Sus* spp.).
k213	TCPA	NA.
k214	Bougainvillea	*Bougainvillea* spp.
k225	Horse radish peroxidase (Arm r HRP)	*Armoracia rusticana*.
k226	Ascorbate oxidase (Cuc p ascorbate oxidase)	*Cucurbita pepo*.
k301	Flour dust	*Triticum* spp.
k501	Savinase customer specific	Proprietary knowledge of customer.
k502	Lipolase customer specific	Proprietary knowledge of customer.
k503	Termamyl customer specific	Proprietary knowledge of customer.
k504	Clazinase customer specific	Proprietary knowledge of customer.

V. Reference

The following reference is on display in the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: July 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–14453 Filed 7–10–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–E–0627 and FDA–2016–E–0629]

Determination of Regulatory Review Period for Purposes of Patent Extension; Intercept Blood System for Platelets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Intercept Blood System for Platelets and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by September 11, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 8, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 11, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2016–E–0627 and FDA–2016–E–0629 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; INTERCEPT BLOOD SYSTEM FOR PLATELETS.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51,