

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 Division of Dockets Management. 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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Stephanie L. Begansky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [AADPAC@fda.hhs.gov](mailto:AADPAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** The committees will discuss new drug application (NDA) 209777, for oxycodone hydrochloride immediate-release oral tablets, submitted by Inspiron Delivery Sciences, LLC., with

the proposed indication of management of moderate to severe pain where the use of an opioid analgesic is appropriate. The product has been formulated with properties intended to deter abuse, and the applicant has submitted data to support these abuse-deterrent properties for this product. The committees will be asked to discuss the overall risk-benefit profile of the product, and whether the applicant has demonstrated abuse-deterrent properties for their product that would support labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** On April 5, 2017, from 9:15 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see the *Addresses* section) on or before March 22, 2017, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 14, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 15, 2017.

**Closed Committee Deliberations:** On April 5, 2017, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

During this session, the committees will discuss the drug development program of an investigational abuse-deterrent opioid product.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2017-N-1062. The docket will close on April 4, 2017. Comments received on or before March 22, 2017, will be provided to the committees. Comments received after that date will be taken into consideration by the Agency.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 9, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-04983 Filed 3-13-17; 8:45 am]

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**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; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has identified a list of class II devices that, when finalized, will be exempt from premarket notification requirements, subject to certain limitations. FDA is publishing this notice of that determination and requesting public comment in accordance with procedures established by the 21st

Century Cures Act. This notice does not represent FDA's final determination with respect to the class II devices included in this document. FDA will review any comments submitted within the 60-day comment period and will consider whether the list of class II devices should be modified prior to publication of its final determination in the **Federal Register**.

**DATES:** Submit either electronic or written comments on the notice by May 15, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 15, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of May 15, 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.

**ADDRESSES:** You may submit comments as follows:

#### *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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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 No. FDA-2017-N-1129 for "Medical Devices; Exemptions from Premarket Notification: Class II Devices." Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets

Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**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, 301-348-1446, email: [Gregory.Bennett@fda.hhs.gov](mailto:Gregory.Bennett@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (1976 amendments) (Pub. L. 94-295), and the amendments of the Safe Medical Devices Act of 1990 (Pub. L. 101-629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the FD&C Act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life sustaining or life supporting device or is for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the FD&C Act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and the implementing regulations, part 807 of Title 21 of the Code of Federal Regulations (CFR), require persons who intend to market a new device to submit a premarket notification (510(k))

containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On December 13, 2016, the President signed into law the 21st Century Cures Act (Pub. L. 114–255). Section 3054 of the 21st Century Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires FDA to 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 to provide reasonable assurance of safety and effectiveness. FDA is required to publish this notice within 90 days of the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Additionally, FDA must provide at least a 60-day comment period for any such notice required to be published under section 510(m)(1)(A) of the FD&C Act. 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 exemption of the devices that were contained in the present list published under section 510(m)(1)(A) of the FD&C Act. Section 510(m)(3) of the FD&C Act provides that upon the date of publication of the final list in the **Federal Register**, a 510(k) will no longer be required for these devices and the classification regulation applicable to each such type of device shall be

deemed amended to incorporate such exemption.

In a final action, and after considering comments, FDA intends to amend the codified language for each listed regulation to reflect the final determination with respect to exempt devices. FDA’s final action 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 510(k) 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 guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (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 initial 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 §§ 862.9 to 892.9) 21 CFR 862.9 to 892.9, FDA may partially limit the exemption from premarket notification requirements to specific devices within a listed device type. In table 1, for example, FDA is listing the exemption of the endoscopic magnetic retriever, but limits the exemption to such devices that are for single use. All other endoscopic magnetic retrievers are still subject to premarket notification requirements because FDA determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices.

**IV. List of Class II Devices**

FDA is identifying the following list of class II devices that, if finalized, would 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	Partial exemption limitation (if applicable)
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	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
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.	PPF	
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	
862.3100 .....	Enzyme Immunoassay, Amphetamine.	DKZ	Exemption is limited to test systems intended for 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 ...	DJP	Exemption is limited to test systems intended for 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.	DIT	Exemption is limited to test systems intended for 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	DOD	Exemption is limited to test systems intended for 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.	DNI	Exemption is limited to test systems intended for 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 ..	DJL	Exemption is limited to test systems intended for 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 ..	DIS	Exemption is limited to test systems intended for 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 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.3150 .....	Radioimmunoassay, Barbiturate .....	DKN	Exemption is limited to test systems intended for 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.	DKX	Exemption is limited to test systems intended for 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.	DJN	Exemption is limited to test systems intended for 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.	DLX	Exemption is limited to test systems intended for 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.	DMF	Exemption is limited to test systems intended for 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.	KZY	Exemption is limited to test systems intended for 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.	JXM	Exemption is limited to test systems intended for 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.	LAA	Exemption is limited to test systems intended for 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 .....	Test, Benzodiazepine, Over The Counter.	NFV	Exemption is limited to test systems intended for 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.	KZZ	Exemption is limited to test systems intended for 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.	LAB	Exemption is limited to test systems intended for 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.).
862.3200 .....	Calibrators, Drug Mixture .....	DKB	
862.3200 .....	Calibrators, Drug Specific .....	DLJ	
862.3200 .....	Calibrators, Ethyl Alcohol .....	DNN	
862.3250 .....	Enzyme Immunoassay, Cocaine and Cocaine Metabolites.	DIO	Exemption is limited to test systems intended for 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.	KLN	Exemption is limited to test systems intended for 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 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.3250 .....	Enzyme Immunoassay, Cocaine .....	JXO	Exemption is limited to test systems intended for 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).	DLN	Exemption is limited to test systems intended for 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.	DMN	Exemption is limited to test systems intended for 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 .....	Free Radical Assay, Cocaine .....	DIR	Exemption is limited to test systems intended for 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 .....	DIN	Exemption is limited to test systems intended for 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.	DOM	Exemption is limited to test systems intended for 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.	LAC	Exemption is limited to test systems intended for 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.	LAE	Exemption is limited to test systems intended for 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.	DLD	Exemption is limited to test systems intended for 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 .....	LAD	Exemption is limited to test systems intended for 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) .....	DLB	Exemption is limited to test systems intended for 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 .....	Free Radical Assay, LSD .....	DOL	Exemption is limited to test systems intended for 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.	LAF	Exemption is limited to test systems intended for 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.	DJC	Exemption is limited to test systems intended for 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 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.3610 .....	High Pressure Liquid Chromatography, Methamphetamine.	LAG	Exemption is limited to test systems intended for 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.	NGG	Exemption is limited to test systems intended for 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 ..	DJR	Exemption is limited to test systems intended for 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.	DIW	Exemption is limited to test systems intended for 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 ....	DMB	Exemption is limited to test systems intended for 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 .....	Thin Layer Chromatography, Methadone.	DKR	Exemption is limited to test systems intended for 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	DNT	Exemption is limited to test systems intended for 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 .....	DPP	Exemption is limited to test systems intended for 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 ..	KXS	Exemption is limited to test systems intended for 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.	DNK	Exemption is limited to test systems intended for 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..	DOE	Exemption is limited to test systems intended for 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 .....	DJJ	Exemption is limited to test systems intended for 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 ....	DPK	Exemption is limited to test systems intended for 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 .....	Gas Chromatography, Morphine .....	DMY	Exemption is limited to test systems intended for 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 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.3640 .....	Hemagglutination Inhibition, Morphine.	DLR	Exemption is limited to test systems intended for 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 .....	DOK	Exemption is limited to test systems intended for 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..	DIQ	Exemption is limited to test systems intended for 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.	DNA	Exemption is limited to test systems intended for 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 .....	DJG	Exemption is limited to test systems intended for 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 .....	DJF	Exemption is limited to test systems intended for 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 .....	DLT	Exemption is limited to test systems intended for 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 .....	Thin Layer Chromatography, Opiates	LAI	Exemption is limited to test systems intended for 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 .....	DKT	Exemption is limited to test systems intended for 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.	LAH	Exemption is limited to test systems intended for 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.	JXN	Exemption is limited to test systems intended for 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.	DPN	Exemption is limited to test systems intended for 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	LAJ	Exemption is limited to test systems intended for 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.	LAK	Exemption is limited to test systems intended for 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 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.3870 .....	Enzyme Immunoassay, Cannabinoids.	LDJ	Exemption is limited to test systems intended for 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 .....	Reagents, Test, Tetrahydrocannabinol.	DKE	Exemption is limited to test systems intended for 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)	LAT	Exemption is limited to test systems intended for 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.	LFI	Exemption is limited to test systems intended for 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.	LFH	Exemption is limited to test systems intended for 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.	MLK	Exemption is limited to test systems intended for 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.).
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	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
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 .....	<i>Alpha</i> -2-Macroglobulin, Rhodamine, Antigen, Antiserum, Control.	DDT	
866.5620 .....	<i>Alpha</i> -2-Macroglobulin, FITC, Antigen, Antiserum, Control.	DDY	
866.5620 .....	<i>Alpha</i> -2-Macroglobulin, Antigen, Antiserum, Control.	DEB	
866.5630 .....	System, Test, <i>Beta</i> -2-Microglobulin Immunological.	JZG	
866.5750 .....	System, Test, Radioallergosorbent (RAST) Immunological.	DHB	Exemption is limited to devices classified under 21 CFR 866.5750 that are intended to detect any of the allergens included in table 2 of this document.
866.5910 .....	Quality Control Material, Genetics, DNA.	NZB	
868.1040 .....	Algesimeter, Powered .....	BSI	
868.1400 .....	Legging, Compression, Non-Inflatable.	LLK	
868.2385 .....	Analyzer, Nitrogen Dioxide .....	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.
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	
870.1330 .....	Wire, Guide, Catheter .....	DQX	Exemption is limited to accessory torque devices that are manually operated, non-patient contacting, and intended to manipulate non-cerebral vascular guide wires.
870.1390 .....	Trocar .....	DRC	
870.1650 .....	Syringe, Balloon Inflation .....	MAV	Exemption is limited to non-patient contacting balloon inflation syringes intended only to inflate/deflate balloon catheters and monitor pressure within the balloon.
870.1875 .....	Lung Sound Monitor .....	OCR	
870.2675 .....	Oscillometer .....	DRZ	
870.2770 .....	Analyzer, Body Composition .....	MNW	Exemption is limited to body composition analyzers which are not intended to diagnose or treat any medical condition.
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	
870.4400 .....	Reservoir, Blood, Cardiopulmonary Bypass.	DTN	Exemption is limited to cardiopulmonary bypass blood reservoirs that do not contain defoamers or blood filters.
870.4420 .....	Sucker, Cardiomyotomy Return, Cardiopulmonary Bypass.	DTS	
870.4430 .....	Suction Control, Intracardiac, Cardiopulmonary Bypass.	DWD	
872.1720 .....	Tester, Pulp .....	EAT	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
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	
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	
874.1090 .....	Tester, Auditory Impedance .....	ETY	Exemption is limited to auditory impedance testers that are in compliance with FDA-recognized consensus standard ANSI S3.39.
874.1090 .....	Tympanometer .....	NAS	Exemption is limited to tympanometers that are in compliance with FDA-recognized consensus standard ANSI S3.39.
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 .....	Endoscopic Magnetic Retriever .....	FCC	Exemption is limited to endoscopic magnetic retrievers intended for single use.
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 .....	Scissors For Cystoscope .....	KGD	Exemption is limited to sterile scissors for cystoscope intended for single use.
876.1500 .....	LED Light Source .....	NTN	
876.1500 .....	Endoscopic Guide Wire, Gastroenterology-Urology.	OCY	
876.1500 .....	Endoscopic Grasping/Cutting Instrument, Non-Powered.	OCZ	Exemption is limited to disposable, non-powered endoscopic grasping/cutting instruments intended for single use.
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 .....	Lithotripter, Biliary Mechanical .....	LQC	
876.4770 .....	Urethrotome .....	EZO	
876.5010 .....	Bag, Bile Collecting .....	EXF	
876.5010 .....	Catheter, Biliary, Surgical .....	GCA	Exemption is limited to surgical biliary catheters that do not include a balloon component.
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	
876.5630 .....	Catheter, Peritoneal, Long-Term Indwelling.	FJS	Exemption is limited to non-patient contacting catheter finger grips intended for single use.
876.5630 .....	Catheter, Peritoneal Dialysis, Single Use.	FKO	Exemption is limited to non-patient contacting catheter finger grips intended for single use.
876.5630 .....	System, Peritoneal, Automatic Delivery.	FKX	Exemption is limited to continuous ambulatory peritoneal dialysis (CAPD) belts and catheter stands that do not include weigh scales.
876.5665 .....	Disinfectant, Subsystem, Water Purification.	NIH	
876.5820 .....	Set, Dialyzer Holder .....	FKI	
876.5895 .....	Irrigator, Ostomy .....	EXD	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
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	
878.4370 .....	Drape, Surgical .....	KKX	Exemption is limited to surgical drapes that do not include an antimicrobial agent.
878.4495 .....	Suture, Nonabsorbable, Steel, Monofilament And Multifilament, Sterile.	GAQ	Exemption is limited to steel monofilament sutures that are uncoated and do not incorporate barbs.
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	
882.1470 .....	Computerized Cognitive Assessment Aid.	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.
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	
884.1630 .....	Colposcope (and Colpomicroscope)	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.
884.2990 .....	Sheet, Recording, Breast Examination.	NHM	
884.3200 .....	Drain, Cervical .....	HFL	
884.4400 .....	Forceps, Obstetrical .....	HDA	
884.4530 .....	Tenaculum, Uterine .....	HDC	Exemption is limited to sterile uterine tenaculum devices that do not use suction and are intended for single use.
884.4530 .....	Clamp, Umbilical .....	HFW	
884.4530 .....	Speculum, Vaginal, Nonmetal .....	HIB	
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	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
884.5425 .....	Pad, Menstrual, Scented .....	HHL	
884.6120 .....	Accessory, Assisted Reproduction ...	MQG	Exemption is limited to single 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).	MQH	Exemption is limited to assisted reproduction microtools (pipettes) manufactured from glass.
884.6150 .....	Micromanipulators and Microinjectors, Assisted Reproduction.	MQJ	
884.6160 .....	Labware, Assisted Reproduction .....	MQK	Exemption is limited to dishes and plates that are intended for general assisted reproduction technology procedures.
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	
886.1850 .....	Biomicroscope, Slit-Lamp, AC-Powered.	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.
886.1945 .....	Transilluminator, AC-Powered .....	HJM	
886.3320 .....	Ocular Peg .....	MQU	Exemption is limited to ocular pegs supplied sterile.
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	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
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 1, FDA included devices classified under § 866.5750 (Radioallergosorbent (RAST) immunological test system, product

code “DHB”). FDA does not believe that all devices with the product code DHB meet the exemption criteria from premarket notification requirements.

However, FDA is identifying a substantial amount of these devices for exemption in table 2.

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)

Allergen code	Allergen product	Source (taxonomical name)
<b>Grass Pollens</b>		
g1 .....	Sweet vernal grass .....	<i>Anthoxanthum odoratum.</i>
g3 .....	Cocksfoot grass, Orchard grass .....	<i>Dactylis glomerata.</i>
g4 .....	Meadow fescue .....	<i>Festuca elatior.</i>
g5 .....	Rye-grass (perennial rye grass) .....	<i>Lolium perenne.</i>
g7 .....	Common reed (common reed grass) .....	<i>Phragmites communis.</i>
g8 .....	Meadow grass, Kentucky blue (June grass) .....	<i>Poa pratensis.</i>
g9 .....	Redtop, Bentgrass .....	<i>Agrostis stolonifera, Agrostis gigantea (Agrostis alba).</i>
g11 .....	Brome grass .....	<i>Bromus inermis.</i>
g12 .....	Cultivated rye (cultivated rye grass) .....	<i>Secale cereale.</i>
g13 .....	Velvet grass .....	<i>Holcus lanatus.</i>
g14 .....	Cultivated oat (cultivated oat grass) .....	<i>Avena sativa.</i>
g15 .....	Cultivated wheat (cultivated wheat grass) .....	<i>Triticum aestivum (Triticum spp.).</i>
g16 .....	Meadow foxtail (meadow foxtail grass) .....	<i>Alopecurus pratensis.</i>
g17 .....	Bahia grass .....	<i>Paspalum notatum.</i>
g24 .....	Wheat grass, Western .....	<i>Agropyron smithii (Elymus smithii).</i>
g30 .....	Bluegrass, annual .....	<i>Poa annua.</i>
g70 .....	Wild rye grass .....	<i>Elymus triticoides, Elymus condensatus.</i>
g71 .....	Canary grass .....	<i>Phalaris arundinacea.</i>
g201 .....	Barley, cultivated .....	<i>Hordeum vulgare.</i>
g202 .....	Maize, corn (cultivated corn) .....	<i>Zea mays.</i>
g203 .....	Salt grass .....	<i>Distichlis spicata.</i>
g204 .....	False oat-grass .....	<i>Arrhenatherum elatius.</i>
g216 .....	Cyn d 1 .....	<i>Cynodon dactylon.</i>
g701 .....	Phl p 1.0102, Phl p 5.0101 .....	<i>Phleum pratense.</i>
g702 .....	Phl p 7.0101 .....	<i>Phleum pratense.</i>
g703 .....	Phl p 12.0101 .....	<i>Phleum pratense.</i>
<b>Weed Pollens</b>		
w2 .....	Western ragweed .....	<i>Ambrosia psilostachya.</i>
w4 .....	False ragweed .....	<i>Ambrosia acanthicarpa (Franseria acanthicarpa).</i>
w5 .....	Wormwood .....	<i>Artemisia absinthium, Artemisia annua.</i>
w6 .....	Mugwort .....	<i>Artemisia vulgaris.</i>
w7 .....	Marguerite, ox-eye daisy .....	<i>Chrysanthemum leucanthemum.</i>
w8 .....	Dandelion .....	<i>Taraxacum vulgare, Taraxacum officinale.</i>
w9 .....	Plantain (English), Ribwort .....	<i>Plantago lanceolata.</i>
w10 .....	Goosefoot, lamb's quarters .....	<i>Chenopodium album.</i>
w11 .....	Saltwort (prickly), Russian thistle .....	<i>Salsola kali (Salsola pestifer).</i>
w12 .....	Goldenrod .....	<i>Solidago virgaurea (Solidago spp.).</i>
w13 .....	Cocklebur, common .....	<i>Xanthium commune.</i>
w14 .....	Common pigweed (rough pigweed) .....	<i>Amaranthus retroflexus.</i>
w15 .....	Scale, Lenscale .....	<i>Atriplex lentiformis.</i>

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
w16	Rough marsh elder	<i>Iva ciliate</i> , <i>Iva annua</i> .
w17	Firebush (Kochia)	<i>Kochia scoparia</i> .
w18	Sheep sorrel	<i>Rumex acetosella</i> .
w19	Wall pellitory	<i>Parietaria officinalis</i> .
w20	Nettle (Common stinging nettle)	<i>Urtica dioica</i> .
w21	Wall pellitory	<i>Parietaria judaica</i> .
w22	Japanese hop (careless weed)	<i>Humulus japonicas</i> ( <i>Humulus scandens</i> ).
w23	Yellow dock, Yellow dockweed	<i>Rumex crispus</i> .
w24	Spiny pigweed	<i>Amaranthus spinosus</i> .
w27	Carnation	<i>Dianthus</i> spp.
w28	Rose	<i>Rosa rugosa</i> .
w33	Clover	<i>Trifolium pratense</i> .
w35	Mexican tea	<i>Chenopodium ambrosioides</i> .
w36	Rabbit bush	<i>Ambrosia deltoidea</i> ( <i>Franseria deltoidea</i> ).
w37	Salt bush, annual	<i>Atriplex wrightii</i> .
w39	Water hemp, Western	<i>Amaranthus rudis</i> ( <i>Acnida tamariscina</i> ).
w41	Burrobrush	<i>Hymenoclea salsola</i> .
w42	Poverty weed.	
w43	Common sagebrush	<i>Artemisia tridentata</i> .
w45	Alfalfa	<i>Medicago sativa</i> .
w46	Dog fennel	<i>Eupatorium capillifolium</i> .
w53	Geranium	<i>Geranium</i> spp.
w67	Groundsel bush	<i>Baccharis halimifolia</i> .
w69	Iodine bush	<i>Allenrolfea occidentalis</i> .
w70	Ragweed, slender	<i>Ambrosia confertiflora</i> .
w75	Wing scale (wingscale)	<i>Atriplex canescens</i> .
w82	Careless weed	<i>Amaranthus palmeri</i> , <i>Amaranthus hybridus</i> .
w90	Japanese hop	<i>Humulus japonicas</i> ( <i>Humulus scandens</i> ).
w203	Rape (rape pollen)	<i>Brassica napus</i> .
w204	Sunflower	<i>Helianthus annuus</i> .
w206	Camomile	<i>Matricaria chamomilla</i> .
w207	Lupin	<i>Lupinus</i> spp.
w210	Sugar-beet	<i>Beta vulgaris</i> .
w211	Par j 2.0101	<i>Parietaria judaica</i> .
w231	Art v 1	<i>Artemisia vulgaris</i> (Mugwort).
w232	Sal k 1	<i>Salsola kali</i> .
w233	Art v 3	<i>Artemisia vulgaris</i> (LTP, Mugwort).
w234	Pla l 1	<i>Plantago lanceolata</i> .
w235	Che a 1.0101	<i>Chenopodium album</i> .
w236	Mer a 1.0101	<i>Mercurialis annua</i> .
a753	Art v 1	<i>Artemisia vulgaris</i> (Mugwort weed).
<b>Tree Pollens</b>		
t1	Box-elder (Maple)	<i>Acer negundo</i> , <i>Acer saccharum</i> .
t2	Gray alder, speckled alder (alder)	<i>Alnus incana</i> .
t4	Hazel, hazelnut	<i>Corylus avellana</i> , <i>Corylus americana</i> .
t5	American beech (beech)	<i>Fagus grandifolia</i> ( <i>Fagus americana</i> ).
t6	Mountain juniper, Mountain cedar	<i>Juniperus ashei</i> ( <i>Juniperus sabinoides</i> ).
t8	Elm	<i>Ulmus americana</i> .
t9	Olive	<i>Olea europaea</i> .
t10	Walnut	<i>Juglans californica</i> , <i>Juglans nigra</i> .
t11	Maple leaf sycamore, London plane, Plane tree	<i>Platanus acerifolia</i> .
t61	Sycamore	<i>Platanus occidentalis</i> .
t12	Willow	<i>Salix caprea</i> , <i>Salix nigra</i> .
t14	Cottonwood (Eastern Cottonwood/Black Cottonwood)	<i>Populus deltoides</i> .
t15	White ash	<i>Fraxinus americana</i> .
t16	White pine	<i>Pinus strobus</i> .
t18	Eucalyptus, gum-tree	<i>Eucalyptus globulus</i> ( <i>Eucalyptus</i> spp.).
t19/t26	Acacia	<i>Acacia longifolia</i> ( <i>Acacia</i> spp.).
t20	Mesquite	<i>Prosopis glandulosa</i> / <i>Prosopis juliflora</i> .
t21	Melaleuca, cajeput tree	<i>Melaleuca quinquenervia</i> ( <i>Melaleuca leucadendron</i> ).
t22	Pecan, hickory	<i>Carya illinoensis</i> ( <i>Carya pecan</i> ).
t23	Italian/Mediterranean/funeral cypress	<i>Cupressus sempervirens</i> .
t24	Japanese cypress	<i>Chamaecyparis obtusa</i> ( <i>Chamaecyparis</i> spp.).
t25	Ash	<i>Fraxinus excelsior</i> .
t27	Maple, red	<i>Acer rubrum</i> .
t29	Acacia	<i>Acacia</i> spp.
t30	Birch, white	<i>Betula populifolia</i> .

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—  
Continued

Allergen code	Allergen product	Source (taxonomical name)
t32	Willow, black	<i>Salix nigra</i> .
t33	Ash, Arizona	<i>Fraxinus velutina</i> .
t35	Cedar, salt	<i>Tamarix gallica</i> .
t37	Bald cypress (white bald cypress)	<i>Taxodium distichum</i> .
t38	Elm, Chinese/Siberian	<i>Ulmus pumila</i> .
t40	Hazelnut tree	<i>Corylus americana</i> .
t41	White hickory	<i>Carya alba</i> ( <i>Carya tomentosa</i> ).
t42	Oak, red	<i>Quercus rubra</i> .
t43	Loblolly pine	<i>Pinus taeda</i> .
t44	Hackberry	<i>Celtis occidentalis</i> .
t45	Cedar elm	<i>Ulmus crassifolia</i> .
t47	Juniper, one seed	<i>Juniperus monosperma</i> .
t48	Pine, lodgepole	<i>Pinus contorta</i> .
t49	Pine, ponderosa	<i>Pinus ponderosa</i> .
t50	Beech, European	<i>Fagus sylvatica</i> .
t51	Tree of Heaven	<i>Ailanthus altissima</i> .
t52	Western white pine	<i>Pinus monticola</i> .
t54	Russian olive	<i>Elaeagnus angustifolia</i> .
t55	Scotch broom	<i>Cytisus scoparius</i> .
t56	Bayberry	<i>Myrica cerifera</i> .
t57	Red cedar	<i>Juniperus virginiana</i> .
t60	Western juniper	<i>Juniperus occidentalis</i> .
t61	Sycamore	<i>Platanus occidentalis</i> .
t70	Mulberry (white mulberry)	<i>Morus alba</i> .
t71	Red mulberry	<i>Morus rubra</i> .
t72	Queen palm	<i>Arecastrum romanzoffianum</i> .
t73	Australian pine	<i>Casuarina equisetifolia</i> .
t77	Oak mix (red, white, black)	<i>Quercus</i> spp.
t80	Japanese cypress	<i>Chamaecyparis obtusa</i> .
t81	Japanese alder	<i>Alnus japonica</i> .
t83	Mango tree	<i>Mangifera indica</i> .
t90	Walnut, black	<i>Juglans nigra</i> .
t96	Poplar, white (poplar)	<i>Populus alba</i> .
t103/t218	Virginia live oak (live oak)	<i>Quercus virginiana</i> .
t105	Pepper tree	<i>Schinus molle</i> .
t110	Orange tree	<i>Citrus sinensis</i> .
t201	Spruce, Norway spruce	<i>Picea abies</i> ( <i>Picea excelsa</i> ).
t202	Alder, smooth	<i>Alnus incana</i> spp. <i>Rugosa</i> ( <i>Alnus rugosa</i> ).
t203	Horse chestnut	<i>Aesculus hippocastanum</i> .
t205	Elder	<i>Sambucus nigra</i> .
t206	Chestnut	<i>Castanea sativa</i> .
t207	Douglas fir	<i>Pseudotsuga menziesii</i> ( <i>Pseudotsuga taxifolia</i> ).
t208	Linden	<i>Tilia cordata</i> .
t209	Horn beam	<i>Carpinus betulus</i> .
t210	Privet	<i>Ligustrum vulgare</i> .
t211	Sweet gum	<i>Liquidambar styraciflua</i> .
t212	Cedar	<i>Libocedrus decurrens</i> .
t213	Pine	<i>Pinus radiata</i> .
t214	Date palm	<i>Phoenix canariensis</i> .
t215	Lilac	<i>Syringa vulgaris</i> .
t217	Pepper tree	<i>Schinus molle</i> .
t217	Red alder	<i>Alnus rubra</i> .
t218	Virginia live oak	<i>Quercus virginiana</i> .
t218	Bayberry (bayberry/sweet gale)	<i>Myrica gale</i> .
t219	Palo verde	<i>Cercidium floridum</i> .
t219	Red cedar	<i>Juniperus virginiana</i> .
t220	Bet v 4	<i>Betula verrucosa</i> (Birch).
t221	Bet v 2.0101, Bet v 4	<i>Betula verrucosa</i> (Birch).
t222	Cypress (Arizona cypress)	<i>Cupressus arizonica</i> .
t223	Oil palm	<i>Elaeis guineensis</i> .
t224	Ole e 1	<i>Olea europaea</i> .
t225	Bet v 6	<i>Betula verrucosa</i> (Birch).
t226	Cup a 1	<i>Cupressus arizonica</i> .
t227	Ole e 7	<i>Olea Europaea</i> .
t228	Aspen, quaking	<i>Populus tremuloides</i> .
t229	Eastern hemlock	<i>Tsuga canadensis</i> .
t230	Redwood (sequoia)	<i>Sequoia sempervirens</i> .
t232	Pussy willow	<i>Salix discolor</i> .
t240	Ole e 9.0101	<i>Olea Europaea</i> .
t241	Pla a 1.0101	<i>Platanus acerifolia</i> .



TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
t242	Pla a 2	<i>Platanus acerifolia</i> .
t243	Pla a 3.0101	<i>Platanus acerifolia</i> .
t244	Cor a 1.0103	<i>Corylus avellana</i> .
t245	Aln g 1.0101	<i>Alnus glutinosa</i> .
t246	Cry j 1	<i>Cryptomeria japonica</i> .
t280	Locust tree	<i>Robinia pseudoacacia</i> .
t401	Brazilian peppertree	<i>Schinus terebinthifolius</i> .
t402	Mastic tree	<i>Pistacia lentiscus</i> .
t404	Tree of heaven	<i>Ailanthus altissima</i> .
t406	Date palm	<i>Phoenix dactylifera</i> .
a482	Ole e 1	<i>Olea europaea</i> (Olive Oil).
<b>Mites</b>		
d207	Blo t 5.0101	<i>Blomia tropicalis</i> .
d208	Lep d 2.0101	<i>Lepidoglyphus destructor</i> .
<b>Microorganisms, Molds, Yeast</b>		
m1	<i>Penicillium chrysogenum</i> ( <i>Penicillium notatum</i> )	<i>Penicillium chrysogenum</i> ( <i>Penicillium notatum</i> ).
m2	<i>Cladosporium herbarum</i> ( <i>Hormodendrum</i> )	<i>Cladosporium herbarum</i> ( <i>Hormodendrum</i> ).
m3	<i>Aspergillus fumigatus</i>	<i>Aspergillus fumigatus</i> .
m4	<i>Mucor racemosus</i>	<i>Mucor racemosus</i> .
m5	<i>Candida albicans</i>	<i>Candida albicans</i> .
m7	<i>Botrytis cinerea</i>	<i>Botrytis cinerea</i> .
m8	<i>Drechslera halodes</i> ( <i>Setomelanomma rostrata</i> , <i>Helminthosporium halodes</i> , <i>Helminthosporium</i> <i>interseminatum</i> ).	<i>Drechslera halodes</i> ( <i>Setomelanomma rostrata</i> , <i>Helminthosporium halodes</i> ).
m9	<i>Fusarium moniliforme</i> ( <i>Fusarium proliferatum</i> )	<i>Fusarium moniliforme</i> ( <i>Fusarium proliferatum</i> ).
m10	<i>Stemphylium botryosum</i>	<i>Stemphylium herbarum</i> ( <i>Stemphylium botryosum</i> ).
m11	<i>Rhizopus nigricans</i>	<i>Rhizopus nigricans</i> .
m12	<i>Aureobasidium pullulans</i>	<i>Aureobasidium pullulans</i> .
m13	<i>Phoma betae</i>	<i>Phoma betae</i> .
m14	<i>Epicoccum purpurascens</i>	<i>Epicoccum purpurascens</i> ( <i>Epicoccum nigrum</i> ).
m15	<i>Trichoderma viride</i>	<i>Trichoderma viride</i> .
m16	<i>Curvularia lunata</i>	<i>Curvularia lunata</i> <i>Curvularia specifera</i> (K923044).
m17	<i>Cladosporium fulvum</i>	<i>Cladosporium fulvum</i> .
m18	<i>Fusarium culmorum</i>	<i>Fusarium culmorum</i> .
m19	<i>Aspergillus versicolor</i>	<i>Aspergillus versicolor</i> .
m20	<i>Mucor mucedo</i>	<i>Mucor mucedo</i> .
m21	<i>Aspergillus clavatus</i>	<i>Aspergillus clavatus</i> .
m22	<i>Micropolyspora faeni</i>	<i>Saccharopolyspora rectivirgula</i> ( <i>Micropolyspora faeni</i> ).
m23	<i>Thermoactinomyces vulgaris</i>	<i>Thermoactinomyces vulgaris</i> .
m24	<i>Stachybotrys atra</i>	<i>Stachybotrys chartarum</i> ( <i>Stachybotrys atra</i> ).
m24	<i>Paecilomyces</i> spp	<i>Paecilomyces</i> spp.
m25	<i>Aspergillus versicolor</i>	<i>Aspergillus versicolor</i> .
m25	<i>Penicillium brevicompactum</i>	<i>Penicillium brevicompactum</i> .
m26	<i>Cladosporium cladosporioides</i>	<i>Cladosporium cladosporioides</i> .
m26	<i>Penicillium citrinum</i>	<i>Penicillium citrinum</i> .
m27	<i>Penicillium</i> spp	<i>Penicillium</i> spp.
m29	<i>Aspergillus repens</i>	<i>Aspergillus repens</i> .
m30	<i>Penicillium roqueforti</i>	<i>Penicillium roqueforti</i> .
m32	<i>Cladosporium cladosporioides</i>	<i>Cladosporium cladosporioides</i> .
m34	<i>Serpula lacrymans</i>	<i>Serpula lacrymans</i> .
m36	<i>Aspergillus terreus</i>	<i>Aspergillus terreus</i> .
m37	<i>Trichophyton mentagrophytes</i>	<i>Trichophyton mentagrophytes</i> .
m40	<i>Aspergillus amstelodami</i>	<i>Aspergillus amstelodami</i> .
m43	<i>Saccharomyces carlsberg</i>	<i>Saccharomyces carlsbergensis</i> .
m44	<i>Saccharomyces cerevisiae</i>	<i>Saccharomyces cerevisiae</i> .
m45	<i>Hormodendrum hordei</i>	<i>Hormodendrum hordei</i> .
m46	<i>Bipolaris spicifera</i>	<i>Bipolaris spicifera</i> .
m47	<i>Aspergillus nidulans</i>	<i>Aspergillus nidulans</i> .
m48	<i>Aspergillus oryzae</i>	<i>Aspergillus oryzae</i> .
m49	<i>Fusarium oxysporum</i>	<i>Fusarium oxysporum</i> .
m50	<i>Micropolyspora faeni</i>	<i>Saccharopolyspora rectivirgula</i> ( <i>Micropolyspora faeni</i> ).
m51	<i>Thermoactinomyces vulgaris</i>	<i>Thermoactinomyces vulgaris</i> .
m53	<i>Microspora canis</i>	<i>Microsporum canis</i> ( <i>Microspora canis</i> ).
m54	<i>Aspergillus flavus</i>	<i>Aspergillus flavus</i> .
m63	<i>Helminthosporium intersemin</i>	<i>Helminthosporium intersemin</i> .
m66	<i>Mucor plumbeus</i>	<i>Mucor plumbeus</i> .

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
m67	<i>Mycogone</i>	<i>Mycogone perniciosa</i> .
m68	<i>Nigrospora oryzae</i>	<i>Nigrospora oryzae</i> .
m69	<i>Rhodotorula</i>	<i>Rhodotorula rubra</i> ( <i>Rhodotorula mucilaginosa</i> ).
m70	<i>Malassezia furfur</i> ( <i>Pityrosporum orbiculare</i> )	<i>Malassezia furfur</i> ( <i>Pityrosporum orbiculare</i> ).
m71	<i>Spondylocladium</i>	<i>Spondylocladium</i> spp.
m72	<i>Epidermophyton</i>	<i>Epidermophyton floccosum</i> .
m73	<i>Epicoccum nigrum</i>	<i>Epicoccum purpurascens</i> ( <i>Epicoccum nigrum</i> ).
m80	<i>Staphylococcal enterotoxin A (Sta a SEA)</i>	<i>Staphylococcus aureus</i> .
m80	<i>Helminthosporium</i> spp	<i>Helminthosporium</i> spp.
m81	<i>Staphylococcal enterotoxin B (Sta a SEB)</i>	<i>Staphylococcus aureus</i> .
m88	<i>Stemphylium solani</i>	<i>Stemphylium solani</i> .
m93	<i>Gliocladium fimbriatum</i>	<i>Gliocladium fimbriatum</i> .
m94	<i>Phycomyces blakesleeianus</i>	<i>Phycomyces blakesleeianus</i> .
m201	<i>Tilletia tritici</i> ( <i>Ustilago nuda</i> , <i>Ustilago tritici</i> ) (Barley smut)	<i>Tilletia tritici</i> ( <i>Ustilago nuda</i> , <i>Ustilago tritici</i> ).
m202	<i>Acremonium kiliense</i> ( <i>Cephalosporium acremonium</i> )	<i>Acremonium kiliense</i> ( <i>Cephalosporium acremonium</i> ).
m203	<i>Trichosporon pullulans</i>	<i>Trichosporon pullulans</i> .
m204	<i>Ulocladium chartarum</i>	<i>Ulocladium chartarum</i> .
m205	<i>Trichophyton rubrum</i>	<i>Trichophyton rubrum</i> .
m207	<i>Aspergillus niger</i>	<i>Aspergillus niger</i> .
m208	<i>Chaetomium globosum</i>	<i>Chaetomium globosum</i> .
m209	<i>Penicillium frequentans</i>	<i>Penicillium glabrum</i> ( <i>Penicillium frequentans</i> ).
m209	<i>Stachybotrys chartarum</i>	<i>Stachybotrys chartarum</i> ( <i>Stachybotrys atra</i> ).
m210	<i>Trichophyton mentagrophytes</i> var. <i>goetzii</i>	<i>Trichophyton mentagrophytes</i> var. <i>goetzii</i> .
m211	<i>Trichophyton mentagrophytes</i> var. <i>interdigitale</i>	<i>Trichophyton mentagrophytes</i> var. <i>interdigitale</i> .
m211	Oat smut	<i>Ustilago avenae</i> .
m212	<i>Micropolyspora faeni</i>	<i>Saccharopolyspora rectivirgula</i> ( <i>Micropolyspora faeni</i> ).
m212	<i>Geotrichum candidum</i>	<i>Geotrichum candidum</i> .
m213	Bermuda grass smut	<i>Ustilago cynodontis</i> .
m214	Johnson grass smut	<i>Sphacelotheca cruenta</i> .
m215	Corn smut	<i>Ustilago maydis</i> .
m218	Asp f 1.0101	<i>Aspergillus fumigatus</i> .
a3050	Asp r 1	<i>Aspergillus restrictus</i> .
m219	Asp f 2	<i>Aspergillus fumigatus</i> .
m220	Asp f 3.0101	<i>Aspergillus fumigatus</i> .
m221	Asp f 4	<i>Aspergillus fumigatus</i> .
m222	Asp f 6.0101	<i>Aspergillus fumigatus</i> .
m223	<i>Staphylococcal enterotoxin C (Sta a SEC)</i>	<i>Staphylococcus aureus</i> .
m224	<i>Staphylococcal enterotoxin D (Sta a SED)</i>	<i>Staphylococcus aureus</i> .
m226	<i>Staphylococcal enterotoxin TSST (Sta a TSST)</i>	<i>Staphylococcus aureus</i> .
m227	<i>Malassezia</i> spp. ( <i>Pityrosporum</i> spp.)	<i>Malassezia</i> spp. ( <i>Pityrosporum</i> spp.).
m228	<i>Aspergillus flavus</i> .	
m229	Alt a 1.0101	<i>Alternaria alternata</i> ( <i>Alternaria tenuis</i> ).
m230	Alt a 6.0101	<i>Alternaria alternata</i> ( <i>Alternaria tenuis</i> ).
m231	Cl a h 8.0101	<i>Cladosporium herbarum</i> ( <i>Hormodendrum</i> ).
m300	<i>Eurotium</i> spp.	<i>Eurotium</i> spp.
m304	<i>Aspergillus oryzae</i>	<i>Aspergillus oryzae</i> .
m305	<i>Penicillium brevicompactum</i>	<i>Penicillium brevicompactum</i> .
m309	<i>Aspergillus terreus</i>	<i>Aspergillus terreus</i> .
m310	<i>Aspergillus nidulans</i>	<i>Aspergillus nidulans</i> .
m311	<i>Aspergillus flavus</i>	<i>Aspergillus flavus</i> .
m312	<i>Aspergillus clavatus</i>	<i>Aspergillus clavatus</i> .

## Epidermal &amp; Animal

e6	Guinea pig epithelium	<i>Cavia porcellus</i> .
e7	Pigeon droppings	<i>Columba palumbus</i> , <i>Columba livia</i> .
e25	Chicken serum	<i>Gallus domesticus</i> ( <i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.).
e26	Parrot serum	<i>Psittacoidea</i> spp.
e62	Camel	<i>Camelus dromedaries</i> .
e70	Goose feathers	<i>Anser anser</i> .
e71	Mouse epithelium	<i>Mus musculus</i> ( <i>Mus</i> spp.).
e73	Rat epithelium	<i>Rattus norvegicus</i> .
e74	Rat urine proteins	<i>Rattus norvegicus</i> <i>Rattus rattus</i> .
e75	Rat serum proteins	<i>Rattus norvegicus</i> <i>Rattus rattus</i> .
e76	Mouse serum proteins	<i>Mus musculus</i> ( <i>Mus</i> spp.).
e77	Budgerigar droppings	<i>Melopsittacus undulatus</i> .
e78	Budgerigar feathers	<i>Melopsittacus undulatus</i> .
e79	Budgerigar serum proteins	<i>Melopsittacus undulatus</i> .
e80	Goat epithelium	<i>Capra hircus</i> .

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
e81	Sheep epithelium	<i>Ovis aries</i> ( <i>Ovis</i> spp.).
e82	Rabbit epithelium	<i>Oryctolagus cuniculus</i> ( <i>Oryctolagus</i> spp.).
e83	Swine epithelium	<i>Sus scrofa</i> ( <i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.).
e84	Hamster epithelium	<i>Cricetus cricetus</i> , <i>Mesocricetus auratus</i> , and <i>Phodopus sungorus</i> .
e85	Chicken feathers	<i>Gallus domesticus</i> ( <i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.).
e86	Duck feathers	<i>Anas platyrhynchos</i> .
e87	Rat epithelium, serum proteins, and urine proteins	<i>Rattus norvegicus</i> <i>Rattus rattus</i> .
e88	Mouse epithelium, serum proteins, and urine proteins (mouse).	<i>Mus musculus</i> ( <i>Mus</i> spp.).
e89	Turkey feathers	<i>Meleagris gallopavo</i> .
e90	Budgerigar serum proteins, feathers, and droppings	<i>Melopsittacus undulatus</i> .
e91	Pigeon serum proteins, feathers, and droppings	<i>Streptopelia roseogrisea</i> <i>Psittacidae</i> spp.
e92	Parrot serum proteins, feathers, and droppings	<i>Ara</i> spp.
e93	Pigeon serum proteins	<i>Streptopelia roseogrisea</i> .
e94	Fel d 1.0101	<i>Felis domesticus</i> .
a345	Fel d 1	<i>Felis domesticus</i> .
e98	Parrot droppings	<i>Psittacoidea</i> spp.
e101	Can f 1.0101	<i>Canis familiaris</i> ( <i>Canis domesticus</i> ).
a174	Can f 1	<i>Canis familiaris</i> ( <i>Canis domesticus</i> ).
e102	Can f 2.0101	<i>Canis familiaris</i> ( <i>Canis domesticus</i> ).
e196	Parakeet feathers	<i>Nymphicus hollandicus</i> .
e197	Parakeet droppings	<i>Nymphicus hollandicus</i> .
e198	Parakeet serum	<i>Nymphicus hollandicus</i> .
e199	Canary bird serum	<i>Serinus canarius</i> .
e200	Canary bird droppings	<i>Serinus canarius</i> .
e201	Canary bird feathers (Canary feathers)	<i>Serinus canarius</i> .
e202	Reindeer epithelium	<i>Rangifer tarandus</i> .
e203	Mink epithelium	<i>Mustela</i> spp.
e204	Bos d 6	<i>Bos domesticus</i> ( <i>Bos taurus</i> ; <i>Bos</i> spp.).
e205	Horse, serum proteins	<i>Equus caballus</i> ( <i>Equus</i> spp.).
e206	Rabbit, serum proteins	<i>Oryctolagus cuniculus</i> ( <i>Oryctolagus</i> spp.).
e208	Chinchilla epithelium	<i>Chinchilla laniger</i> .
e209	Gerbil epithelium	<i>Meriones unguiculatus</i> .
e210	Fox epithelium	<i>Vulpes vulpes</i> .
e211	Rabbit, urine proteins	<i>Oryctolagus cuniculus</i> ( <i>Oryctolagus</i> spp.).
e212	Swine, urine proteins	<i>Sus scrofa</i> ( <i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.).
e213	Parrot feathers	<i>Ara</i> spp.
e214	Finch feathers	<i>Lonchura domestica</i> .
e215	Pigeon feathers	<i>Streptopelia roseogrisea</i> ( <i>Streptopelia</i> spp.), <i>Columbia</i> spp.
e216	Deer epithelium	<i>Dama dama</i> .
e217	Ferret epithelium	<i>Mustela putorius</i> .
e218	Chicken droppings	<i>Gallus domesticus</i> ( <i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.).
e219	Chicken, serum proteins	<i>Gallus domesticus</i> ( <i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.).
e220	Fel d 2, Cat serum albumin	<i>Felis domesticus</i> .
e221	Can f 3	<i>Canis familiaris</i> ( <i>Canis domesticus</i> ) (Dog serum albumin).
e222	Swine serum albumin (Sus s PSA)	<i>Sus scrofa</i> ( <i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.).
e225	Lovebird feathers	<i>Psittacoidea agapomis</i> .
e226	Can f 5.0101	<i>Canis familiaris</i> .
e227	Equ c 1.0101	<i>Equus caballus</i> .
e228	Fel d 4.0101	<i>Felis domesticus</i> .
e230	Equ c 3	<i>Equus caballus</i> .
e231	Mus m 1	<i>Mus musculus</i> .
<b>Food</b>		
f9	Rice	<i>Oryza sativa</i> .
f12	Pea (green pea)	<i>Pisum sativum</i> .
f15	White bean	<i>Phaseolus vulgaris</i> .
f19	Cayenne pepper	<i>Capsicum frutescens</i> , ( <i>Capsicum annuum</i> ).
f21	Sugar cane	<i>Saccharum officinarum</i> .
f22	Raspberry	<i>Rubus idaeus</i> .
f26	Pork	<i>Sus scrofa</i> ( <i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.).
f29	Watermelon	<i>Citrullus lanatus</i> ( <i>Citrullus vulgaris</i> ).
f31	Carrot	<i>Daucus carota</i> .
f32	Oyster mushroom	<i>Pleurotus ostreatus</i> .

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—  
Continued

Allergen code	Allergen product	Source (taxonomical name)
f33	Orange	<i>Citrus sinensis</i> .
f35	Potato	<i>Solanum tuberosum</i> .
f43	Mother's milk	<i>Homo sapiens</i> .
f44	Strawberry	<i>Fragaria vesca</i> ( <i>Fragaria</i> spp.).
f45	Yeast, baker's	<i>Saccharomyces cerevisiae</i> .
f46	Pepper, Red	<i>Capsicum annuum</i> .
f47	Garlic	<i>Allium sativum</i> .
f48	Onion	<i>Allium cepa</i> .
f49	Apple	<i>Malus x domestica</i> ( <i>Malus</i> spp.).
f51	Bamboo shoot	<i>Phyllostachys pubescens</i> .
f52	Cacao/chocolate	<i>Theobroma cacao</i> .
f54	Sweet potato	<i>Ipomoea batatas</i> .
f55	Common millet	<i>Panicum miliaceum</i> .
f56	Foxtail millet	<i>Setaria italica</i> .
f57	Japanese millet	<i>Echinochloa crus-galli</i> .
f58	Pacific squid	<i>Todarodes pacificus</i> .
f59	Octopus	<i>Octopus vulgaris</i> ( <i>Octopus</i> spp.).
f63	Kefir	NA.
f67	Parmesan cheese	NA.
f81	Cheese, cheddar type	NA.
f82	Cheese, mold type	NA.
f83	Chicken	<i>Gallus domesticus</i> ( <i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.).
f86	Parsley	<i>Petroselinum crispum</i> .
f87	Melon	<i>Cucumis melo Cucumis melo + Citrullus lanatus</i> .
f88	Mutton (lamb)	<i>Ovis aries</i> ( <i>Ovis</i> spp.).
f90	Malt	<i>Hordeum vulgare</i> .
f92	Banana	<i>Musa</i> spp.
f93	Cacao	<i>Theobroma cacao</i> .
f94	Pear	<i>Pyrus communis</i> ( <i>Pyrus</i> spp.).
f97	Yam	<i>Dioscorea</i> spp., <i>Dioscorea opposita</i> .
f97	Chamomile tea	<i>Matricaria chamomilla</i> .
f98	Gliadin	<i>Triticum aestivum</i> ( <i>Triticum</i> spp.).
f102	Cantaloupe	<i>Cucumis melo var. cantalupensis</i> .
f105	Chocolate	<i>Theobroma cacao</i> .
f109	Cottonseed	<i>Gossypium hirsutum</i> .
f110	Giant radish	<i>Raphanus sativus</i> .
f118	Zucchini	<i>Cucurbita pepo</i> .
f119	Radish	<i>Raphanus sativus</i> .
f120	Venison	<i>Capreolus capeolus</i> .
f121	Pinto bean	<i>Phaseolus vulgaris</i> .
f122	Cheese, American	NA.
f127	Black-eyed pea	<i>Vigna unguiculata</i> .
f131	Black Olive	<i>Olea europaea</i> .
f136	Red beet	<i>Beta vulgaris var. conditiva</i> .
f139	Goat's Cheese	<i>Capra aegagrus</i> .
f140	Bran	NA.
f141	Corn (vegetables)	<i>Zea mays</i> .
f152	Green bell pepper	<i>Capsicum annuum</i> .
f155	Brewer's yeast	<i>Saccharomyces carlsbergensis</i> .
f157	Duck	<i>Anas domesticus</i> .
f158	Goose	<i>Anser anser</i> .
f160	Camembert cheese	NA.
f162	Nectarine	<i>Prunus persica var. nucipersica</i> .
f163	Kohlrabi	<i>Brassica oleracea var. gongylodes</i> .
f65	Perch	
f166	Leek	<i>Allium porrum</i> .
f170	Cheese (Switzerland) (Swiss cheese)	NA.
f174	Fig	<i>Ficus carica</i> .
f177	Cranberry	<i>Vaccinium macrocarpon</i> .
f179	Raisin	<i>Vitis</i> spp.
f182	Lima bean	<i>Phaseolus lunatus</i> .
f198	Flaxseed (bruised grain)	<i>Linum usitatissimum</i> .
f199	Untreated native milk	<i>Bos domesticus</i> ( <i>Bos taurus</i> ; <i>Bos</i> spp.).
f208	Lemon	<i>Citrus limon</i> .
f209	Grapefruit	<i>Citrus paradisi</i> .
f210	Pineapple	<i>Ananas comosus</i> .
f211	Blackberry	<i>Rubus fruticosus</i> .
f212	Mushroom (champignon)	<i>Agaricus hortensis</i> ( <i>Agaricus</i> spp.).
f213	Rabbit	<i>Oryctolagus cuniculus</i> ( <i>Oryctolagus</i> spp.).

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—  
Continued

Allergen code	Allergen product	Source (taxonomical name)
f214	Spinach	<i>Spinacia oleracea</i> .
f215	Lettuce	<i>Lactuca sativa</i> .
f216	Cabbage	<i>Brassica oleracea</i> var. <i>capitata</i> .
f217	Brussels sprouts	<i>Brassica oleracea</i> var. <i>gem</i> .
f218	Paprika, sweet pepper	<i>Capsicum annuum</i> .
f219	Fennel seed	<i>Foeniculum vulgare</i> .
f219	Sage	<i>Salvia officinalis</i> .
f220	Cinnamon	<i>Cinnamomum</i> spp.
f221	Coffee	<i>Coffea</i> spp.
f222	Tea	<i>Camellia sinensis</i> .
f223	Green olive	<i>Olea europaea</i> .
f225	Summer squash, pumpkin	<i>Cucurbita pepo</i> .
f225	Pumpkin	<i>Cucurbita maxima</i> .
f226	Pumpkin seed	<i>Cucurbita pepo</i> .
f227	Sugar-beet seed	<i>Beta vulgaris</i> .
f229	Safflower Seed	<i>Carthamus tinctorius</i> .
f231	Milk, boiled	<i>Bos domesticus</i> ( <i>Bos taurus</i> ; <i>Bos</i> spp.).
f234	Vanilla	<i>Vanilla planifolia</i> .
f237	Apricot	<i>Prunus armeniaca</i> .
f241	Gouda cheese	NA.
f242	Cherry	<i>Prunus avium</i> .
f244	Cucumber	<i>Cucumis sativus</i> .
f246	Guar, guar gum	<i>Cyamopsis tetragonoloba</i> .
f247	Honey	NA.
f248	Rosemary	<i>Rosmarinus officinalis</i> .
f254	Plaice	<i>Pleuronectes platessa</i> .
f255	Plum	<i>Prunus domestica</i> , <i>Prunus americana</i> .
f258	Squid	<i>Loligo</i> spp.
f259	Grape	<i>Vitis vinifera</i> ( <i>Vitis</i> spp.).
f260	Broccoli	<i>Brassica oleracea</i> var. <i>italica</i> ( <i>Brassica oleracea</i> var. <i>cultivar</i> ).
f261	Asparagus	<i>Asparagus officinalis</i> .
f262	Aubergine, eggplant	<i>Solanum melongena</i> .
f263	Green pepper	<i>Piper nigrum</i> , <i>Capsicum annuum</i> .
f264	Eel	<i>Anguilla anguilla</i> .
f265	Caraway	<i>Carum carvi</i> .
f265	Cumin	<i>Cuminum cyminum</i> .
f266	Mace	<i>Myristica fragrans</i> .
f267	Cardamon	<i>Elettaria cardamomum</i> .
f268	Clove	<i>Syzygium aromaticum</i> .
f269	Basil	<i>Ocimum basilicum</i> .
f270	Ginger	<i>Zingiber officinale</i> .
f271	Anise	<i>Pimpinella anisum</i> .
f272	Tarragon	<i>Artemisia dracunculus</i> .
f273	Thyme	<i>Thymus vulgaris</i> .
f274	Marjoram	<i>Origanum majorana</i> .
f275	Lovage	<i>Levisticum officinale</i> .
f276	Fennel, fresh	<i>Foeniculum vulgare</i> .
f277	Dill	<i>Anethum graveolens</i> .
f278	Bay leaf	<i>Laurus nobilis</i> .
f279	Chili pepper	<i>Capsicum frutescens</i> .
f280	Black pepper	<i>Piper nigrum</i> .
f281	Curry (Santa Maria)	NA.
f282	Nutmeg	<i>Myristica fragrans</i> .
f283	Oregano	<i>Origanum vulgare</i> .
f284	Turkey meat	<i>Meleagris gallopavo</i> .
f285	Elk/moose meat	<i>Alces</i> spp.
f286	Mare's milk	<i>Equus caballus</i> ( <i>Equus</i> spp.).
f287	Red kidney bean	<i>Phaseolus vulgaris</i> .
f288	Blueberry	<i>Vaccinium myrtillus</i> ( <i>Vaccinium</i> spp.).
f289	Date	<i>Phoenix dactylifera</i> .
f291	Cauliflower	<i>Brassica oleracea</i> var. <i>botrytis</i> .
f292	Guava	<i>Psidium guajava</i> .
f293	Papaya	<i>Carica papaya</i> .
f294	Passion fruit, Maracuja	<i>Passiflora edulis</i> ( <i>Passiflora</i> spp.).
f295	Carambola	<i>Averrhoa carambola</i> .
f296	Carob	<i>Ceratonia siliqua</i> .
f297	Gum arabic	<i>Acacia senegal</i> ( <i>Acacia</i> spp.).
f298	Tragacanth	<i>Astragalus</i> spp.
f299	Sweet chestnut (chestnut)	<i>Castanea sativa</i> .

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
f300	Pinto bean	<i>Phaseolus</i> spp.
f301	Persimmon (kaki fruit, sharon)	<i>Diospyros kaki</i> .
f302	Mandarin (tangerine, clementine, satsumas)	<i>Citrus reticulata</i> .
f305	Fenugreek	<i>Trigonella foenum-graecum</i> .
f306	Lime	<i>Citrus aurantifolia</i> .
f307	Hake	<i>Merluccius merluccius</i> .
f308	Sardine (pilchard)	<i>Sardina pilchardus</i> .
f310	Blue vetch	<i>Lathyrus sativus</i> .
f311	Megrim	<i>Lepidorhombus whiffiagonis</i> .
f315	Green bean	<i>Phaseolus vulgaris</i> .
f316	Rape seed	<i>Brassica napus</i> .
f317	Coriander	<i>Coriandrum sativum</i> .
f318	Jack fruit	<i>Artocarpus heterophyllus</i> .
f319	Beetroot	<i>Beta vulgaris</i> .
f320	Crayfish	<i>Astacus astacus</i> .
f321	Horse meat	<i>Equus caballus</i> ( <i>Equus</i> spp.).
f322	Red currant	<i>Ribes sylvestre</i> .
f324	Hop (fruit cone)	<i>Humulus lupulus</i> .
f325	Saffron	<i>Colchicum autumnale</i> .
f328	Fig	<i>Ficus carica</i> .
f329	Watermelon	<i>Citrullus lanatus</i> .
f330	Rose hip	<i>Rosa</i> spp.
f331	Saffron	<i>Crocus sativus</i> .
f332	Mint	<i>Mentha piperita</i> .
f333	Linseed	<i>Linum usitatissimum</i> .
f336	Jujube	<i>Ziziphus jujuba</i> .
f336	Wine vinegar	<i>Vitis vinifera</i> ( <i>Vitis</i> spp.).
f337	Sole	<i>Solea solea</i> .
f337	English sole	<i>Parophrys vetulus</i> .
f338	Wine, white	<i>Vitis vinifera</i> ( <i>Vitis</i> spp.).
f339	Allspice	<i>Pimenta dioica</i> .
f339	Wine, red	<i>Vitis vinifera</i> ( <i>Vitis</i> spp.).
f341	Cranberry	<i>Vaccinium oxycoccus</i> , <i>Vaccinium macrocarpon</i> .
f342	Olive (black, fresh)	<i>Olea europaea</i> .
f343	Raspberry	<i>Rubus idaeus</i> .
f344	Sage	<i>Salvia officinalis</i> .
f346	Chives	<i>Allium schoenoprasum</i> .
f347	Quinoa	<i>Chenopodium quinoa</i> .
f348	Litchi	<i>Litchi chinensis</i> .
f349	Chum salmon roe	<i>Oncorhynchus keta</i> .
f358	Artichoke	<i>Cynara scolymus</i> .
f360	Yogurt	NA.
f368	Black bass	<i>Micropterus dolomieu</i> ( <i>Micropterus dolomieu</i> ).
f374	Karaya gum	<i>Sterculia urens</i> .
f375	Horseradish	<i>Armoracia rusticana</i> .
f377	Maple syrup	NA.
f379	Okra	<i>Abelmoschus esculentus</i> .
f382	Beet, sugar	<i>Beta vulgaris</i> var. <i>altissima</i> .
f401	Loquat	<i>Eriobotrya japonica</i> .
f402	Fig	<i>Ficus carica</i> .
f403	Brewer's yeast	<i>Saccharomyces cerevisiae</i> .
f405	Mint	<i>Mentha</i> spp.
f406	Arugula	<i>Eruca vesicaria</i> .
<b>House Dust</b>		
h1	Greer Labs., Inc	NA.
h2	Hollister-Stier Labs	NA.
h6	Japan	NA.
<b>Venoms &amp; Insects</b>		
i7	Midge	<i>Chironomus yoshimatsui</i> .
i8	Moth	<i>Bombyx mori</i> , <i>Heterocera</i> spp.
i47	Water flea	<i>Daphnia</i> spp.
i49	Deer fly	<i>Chrysops</i> spp.
i51	Black ant	<i>Camponotus pennsylvanicus</i> .
i54	Flea mix (dog/cat), common flea	<i>Ctenocephalides</i> spp.
i71	Mosquito	<i>Aedes communis</i> , <i>Aedes</i> spp. and <i>Culex</i> spp.
i72	Green nimitti	<i>Cladotanytarsus lewisi</i> .

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
i73	Blood worm	<i>Chironomus thummi</i> , <i>Chironomusri parius</i> , <i>Chironomus</i> spp.
i75	European hornet	<i>Vespa crabro</i> .
i76	Berlin beetle	<i>Trogoderma angustum</i> .
i77	European paper wasp	<i>Polistes dominulus</i> .
i78	Fly	<i>Musca domestica</i> .
i80	Bumblebee	<i>Bombus pennsylvanicus</i> .
i201	Horse bot fly	<i>Gasterophilus intestinalis</i> .
i202	Grain weevil	<i>Sitophilus granarius</i> .
i203	Mediterranean flour moth	<i>Ephestia kuehniella</i> ( <i>Anagasta kuehniella</i> ).
i204	Horse fly	<i>Tabanus</i> spp.
i205	Bumblebee	<i>Bombus terrestris</i> .
i208	Api m 1.0101	<i>Apis mellifera</i> .
a45	Api m 1	<i>Apis mellifera</i> .
i209	Ves v 5.0101	<i>Vespula vulgaris</i> .
a670	Ves v 5	<i>Vespula vulgaris</i> .
i210	Pol d 5.0101	<i>Polistes dominulus</i> .
i211	Ves v 1.0101	<i>Vespula vulgaris</i> .
i213	Api m 4	<i>Apis mellifera</i> .
i214	Api m 2	<i>Apis mellifera</i> .
i215	Api m 3	<i>Apis mellifera</i> .
i216	Api m 5	<i>Apis mellifera</i> .
i217	Api m 10	<i>Apis mellifera</i> .
i220	Bla g 1.0101	<i>Blattella germanica</i> .
i221	Bla g 2.0101	<i>Blattella germanica</i> .
i222	Bla g 5.0101	<i>Blattella germanica</i> .
i223	Bla g 7	<i>Blattella germanica</i> .
a46	Api m 2	<i>Apis mellifera</i> .
<b>Miscellaneous</b>		
o1	Cotton, crude fibers	<i>Gossypium</i> spp.
o3	Cotton (treated)	<i>Gossypium</i> spp.
o70	Seminal fluid	<i>Homo sapiens</i> .
o71	<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i> .
o72	<i>Pichia pastoris</i> crude extract customer specific	<i>Pichia pastoris</i> .
o72	Sperm-sediment	<i>Homo sapiens</i> .
o73	<i>Pichia pastoris</i> crude extr. vector customer specific	<i>Pichia pastoris</i> .
o74	<i>Pichia pastoris</i> with vector customer specific	<i>Pichia pastoris</i> .
o201	Tobacco leaf, tobacco dust	<i>Nicotiana tabacum</i> .
o202	Artemia salina, fish feed	<i>Artemia salina</i> .
o203	Tetramin, fish feed	NA.
o207	Daphnia, fish feed	<i>Daphnia</i> spp.
o211	Mealworm	<i>Tenebrio molitor</i> .
o212	Streptavidin	<i>Streptomyces avidini</i> .
o213	MBP (maltose binding protein)	<i>Escherichia coli</i> .
o214	CCD; MUXF3 from bromelain	<i>Ananas comosus</i> .
o72	Enterotoxin A (Sta a SEA)	<i>Staphylococcus aureus</i> .
o73	Enterotoxin B (Sta a SEB)	<i>Staphylococcus aureus</i> .
<b>Parasites</b>		
p1	Ascaris	<i>Ascaris suum</i> .
p2	Echinococcus	<i>Echinococcus granulosus</i> .
p3	Schistosoma	<i>Schistosoma mansoni</i> .
p4	Anisakis (Herring Worm)	<i>Anisakis simplex</i> ( <i>Anisakis</i> spp.).
p5	Toxocara canis	<i>Toxocara canis</i> .
p10	Ani s 3.0101	<i>Anisakis simplex</i> ( <i>Anisakis</i> spp.).
p11	Ani s 1	<i>Anisakis simplex</i> ( <i>Anisakis</i> spp.).
<b>Occupational</b>		
k4	Threshing dust	NA.
k5	Flax	NA.
k7	Hay Dust	NA.
k8	Hop (hops)	<i>Humulus lupulus</i> .
k12	Grain mill dust	NA.
k14	Kapok	NA.
k20	Sheep's wool (treated) (wool)	<i>Ovis aries</i> ( <i>Ovis</i> spp.).
k21	Sheep's wool (Untreated)	<i>Ovis aries</i> ( <i>Ovis</i> spp.).

TABLE 2—CLASS II DEVICES (§ 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS)—Continued

Allergen code	Allergen product	Source (taxonomical name)
k23	Straw Dust	NA.
k33	Oak	NA.
k70	Green coffee bean	<i>Coffea</i> spp.
k71	Castor bean	<i>Ricinus communis</i> .
k72	Ispaghula	<i>Plantago psyllium/Plantago ovata</i> .
k73	Silk waste	NA.
k74	Silk	<i>Bombyx mori</i> .
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	<i>Ficus benjamina (Ficus spp.)</i> .
k83	Cotton seed	<i>Gossypium hirsutum</i> .
k84	Sunflower seed	<i>Helianthus annuus</i> .
k85	Chloramin T	NA.
k86	Trimellitic anhydride, TMA	NA.
k87	Asp o 21, alpha-amylase	<i>Aspergillus oryzae</i> .
k89	Orris root	<i>Iris florentina</i> .
k99	HSA (Human Serum Albumin) (Homo s HSA)	<i>Homo sapiens</i> .
k201	Car p 1, Papain	<i>Carica papaya</i> .
k202	Ana c 2, Bromelain	<i>Ananas comosus</i> .
k204	Maxatase	<i>Bacillus licheniformis</i> .
k205	Alcalase	<i>Bacillus</i> spp.
k206	Savinase, Protease 1 (Bac I Subtilisin)	<i>Bacillus</i> spp.
k208	Gal d 4, Lysozyme	<i>Gallus domesticus (Gallus gallus domesticus; Gallus spp.)</i> .
k209	Hexahydrophthalic anhydrid	NA.
k210	Maleic anhydride	NA.
k211	Methyltetrahydrophthalic anhydrid	NA.
k212	Abachi wood dust	<i>Triplochiton scleroxylon</i> .
k213	Pepsin (Sus s Pepsin)	<i>Sus scrofa (Sus scrofa domesticus; Sus spp.)</i> .
k213	TCPA	NA.
k214	Bougainvillea	<i>Bougainvillea</i> spp.
k225	Horse radish peroxidase (Arm r HRP)	<i>Armoracia rusticana</i> .
k226	Ascorbate oxidase (Cuc p ascorbate oxidase)	<i>Cucurbita pepo</i> .
k301	Flour dust	<i>Triticum</i> 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 Division of Dockets Management (see ADDRESSES) 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: March 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0455]

Enhancing Patient Engagement Efforts Across the Food and Drug Administration; Establishment of a Public Docket; Request for Comments

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to solicit

input on ongoing efforts to enhance mechanisms for patient engagement at the Agency. Engaging with patients, their caregivers, and advocates has long been a priority of the Agency. In this tradition, FDA intends to enhance future patient engagement by providing a more transparent, accessible, and robust experience for patient communities. To achieve these goals, FDA is considering establishing a new Office of Patient Affairs. This concept was directly informed by the public feedback solicited through the prior public docket regarding FDA's stakeholder engagement responsibilities outlined by the Food and Drug Administration Safety and Innovation Act (FDASIA). The purpose of this notice is to outline FDA's proposal for the future of patient engagement at the Agency so that the perspectives of