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[Notices]
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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

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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.

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))

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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 Sec. Sec. 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 Sec. Sec. 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,	CJX

	Disodium Phenylphosphat e.		
862.1020.....	Acid Phosphatase, Naphthyl Phosphate.	CKB
862.1020.....	Acid Phosphatase, Thymolphthale Inmonophosphat e.	CKE
862.1020.....	Acid Phosphatase, Beta Glycerophospha te.	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
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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.....	Radioimmunoassa y, Thyroxine- Binding Globulin.	CEE
862.1700.....	Radioimmunoassa y, Total Thyroxine.	CDX
862.1700.....	Enzyme Immunoassay,	KLI

862.2265.....	Non-Radiolabeled, Total Thyroxine. High Throughput DNA Sequence Analyzer.	PFF
862.2570.....	Instrumentation For Clinical Multiplex Test Systems.	NSU
862.2570.....	Real Time Nucleic Acid Amplification System.	OOI
862.2570.....	Mass Spectrometer For Clinical Multiplex Test Systems.	OTA
862.2570.....	Micro Total Analysis Instrument System.	OUE
862.2570.....	Complete Gene Expression Profiling Accessory Reagents.	OVA
862.2570.....	DNA Genetic Analyzer.	PCA
862.2570.....	Data Acquisition Software.	PQQ
862.3100.....	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

862.3100.....	Gas Chromatography, Amphetamine.	DOD	<p>(e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.).</p> <p>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.).</p>
862.3100.....	Liquid Chromatography, Amphetamine.	DNI	<p>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.).</p>
862.3150.....	Enzyme Immunoassay, Barbiturate.	DJL	<p>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.).</p>
862.3150.....	Enzyme Immunoassay, Barbiturate.	DIS	<p>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</p>

Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.).

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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

862.3150.....	Gas Liquid Chromatography , Barbiturate.	DMF	Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.). 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

862.3170.....	Test, Benzodiazepine , Over The Counter.	NFV	(DOT), and the U.S. military.). 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

862.3250.....	Radioimmunoassay, Cocaine Metabolite.	KLN	<p>Department of Transportation (DOT), and the U.S. military.).</p> <p>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.).</p>
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862.3250.....	Enzyme Immunoassay, Cocaine.	JXO	<p>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.).</p>
862.3250.....	Hemagglutination, Cocaine Metabolites (Benzoyllecgonine).	DLN	<p>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.).</p>
862.3250.....	Thin Layer Chromatography, Cocaine.	DMN	<p>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</p>

862.3250.....	Free Radical Assay, Cocaine.	DIR	Department of Transportation (DOT), and the U.S. military.). 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.....	Radioimmunoassa y, 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

862.3610.....	Gas Chromatography, Methamphetamine.	LAF	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.). 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.).
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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

862.3620.....	Enzyme Immunoassay, Methadone.	DJR	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.).
			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

862.3620.....	Liquid Chromatography, Methadone.	DNT	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.).
			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

862.3640.....	Radioimmunoassay, Morphine (123-I), Goat Antibody Ammonium Sulfate Sep..	DOE	Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.). 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.).

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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

862.3650.....	Enzyme Immunoassay, Opiates.	DJG	<p>Department of Transportation (DOT), and the U.S. military.).</p> <p>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.).</p>
862.3650.....	Gas Chromatography , Opiates.	DJF	<p>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.).</p>
862.3650.....	Hemagglutinatio n, Opiates.	DLT	<p>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.).</p>
862.3650.....	Thin Layer Chromatography , Opiates.	LAI	<p>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.).</p>

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

862.3700.....	High Pressure Liquid Chromatography , Propoxyphene.	LAK	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.). 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.).
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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, Tetrahydrocann abinol.	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.....	Radioimmunoassa y, 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	GGN

864.5425.....	Control. 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

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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- Ene diamine/ EDTA (Spectrophotom etric), Ceruloplasmin.	JFQ
866.5210.....	Indirect Copper Assay, Ceruloplasmin.	JFR
866.5470.....	Hemoglobin, Chain Specific, Antigen, Antiserum, Control.	DAM
866.5620.....	Alpha-2- Macroglobulin, Rhodamine, Antigen, Antiserum, Control.	DDT
866.5620.....	Alpha-2- Macroglobulin, FITC, Antigen, Antiserum, Control.	DDY
866.5620.....	Alpha-2- Macroglobulin, Antigen, Antiserum, Control.	DEB
866.5630.....	System, Test, Beta-2- Microglobulin Immunological.	JZG
866.5750.....	System, Test, Radioallergoso rbent (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,	LLK

868.2385.....	Compression, Non-Inflatable. 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.....	Pneumotachomete r.	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, Cardiopulmonar y Bypass.	KRJ
870.4290.....	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonar y Bypass.	DTL
870.4340.....	Monitor and/or Control, Level Sensing, Cardiopulmonar y Bypass.	DTW
870.4400.....	Reservoir, Blood,	DTN	Exemption is limited to cardiopulmonary

	Cardiopulmonar y Bypass.		bypass blood reservoirs that do not contain defoamers or blood filters.
870.4420.....	Sucker, Cardiotomy Return, Cardiopulmonar y Bypass.	DTS
870.4430.....	Suction Control, Intracardiac, Cardiopulmonar y Bypass.	DWD
872.1720.....	Tester, Pulp...	EAT
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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.....	Electroglottogr aph.	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, Gastroenterolo gy-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.....	Lithotriptor, 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 Gastrointestin al, Gastro- Urology.	FAT
876.5365.....	Dilator, Esophageal.	KNQ
876.5520.....	Dilator,	KOE

876.5630.....	Urethral. 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

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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,	FSX

878.4580.....	Surgical, Connector. 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.	H CJ
882.1855.....	Encephalogram Telemetry System.	GYE
882.5895.....	Vibratory Counter- Stimulation.	OVP
884.1630.....	Colposcope (and Colpomicroscop e).	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 urterine 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
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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.....	Micromanipulato rs 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.....	Transilluminato r, AC-Powered.	HJM
886.3320.....	Ocular Peg.....	MQU	Exemption is limited to ocular pegs supplied sterile.
886.4150.....	Tubing, Replacement, Phacofragmenta tion 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-	ILJ

890.5100.....	Massage. 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
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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	LMC

892.2040.....	Format, Radiological. Device, Hardcopy, Images, Ophthalmic.	NFI
892.5730.....	Prostate Seeding Kit.	OIN

In table 1, FDA included devices classified under Sec. 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 (Sec. 866.5750--Radioallergosorbent (RAST) Immunological Test Systems)

Allergen code	Allergen product	Source (taxonomical name)
Grass Pollens		
g1.....	Sweet vernal grass...	Anthoxanthum odoratum.
g3.....	Cocksfoot grass, Orchard grass.	Dactylis glomerata.
g4.....	Meadow fescue.....	Festuca elatior.
g5.....	Rye-grass (perennial rye grass).	Lolium perenne.
g7.....	Common reed (common reed grass).	Phragmites communis.
g8.....	Meadow grass, Kentucky blue (June grass).	Poa pratensis.
g9.....	Redtop, Bentgrass....	Agrostis stolonifera, Agrostis gigantea (Agrostis alba).
g11.....	Brome grass.....	Bromus inermis.
g12.....	Cultivated rye (cultivated rye grass).	Secale cereale.
g13.....	Velvet grass.....	Holcus lanatus.
g14.....	Cultivated oat (cultivated oat grass).	Avena sativa.
g15.....	Cultivated wheat (cultivated wheat grass).	Triticum aestivum (Triticum spp.).
g16.....	Meadow foxtail (meadow foxtail grass).	Alopecurus pratensis.
g17.....	Bahia grass.....	Paspalum notatum.
g24.....	Wheat grass, Western.	Agropyron smithii (Elymus smithii).
g30.....	Bluegrass, annual....	Poa annua.
g70.....	Wild rye grass.....	Elymus triticoides, Elymus condensatus.
g71.....	Canary grass.....	Phalaris arundinacea.
g201.....	Barley, cultivated...	Hordeum vulgare.
g202.....	Maize, corn (cultivated corn).	Zea mays.
g203.....	Salt grass.....	Distichlis spicata.
g204.....	False oat-grass.....	Arrhenatherum elatius.
g216.....	Cyn d 1.....	Cynodon dactylon.
g701.....	Phl p 1.0102, Phl p 5.0101.	Phleum pratense.
g702.....	Phl p 7.0101.....	Phleum pratense.
g703.....	Phl p 12.0101.....	Phleum pratense.
Weed Pollens		
w2.....	Western ragweed.....	Ambrosia psilostachya.
w4.....	False ragweed.....	Ambrosia acanthicarpa (Franseria acanthicarpa).
w5.....	Wormwood.....	Artemisia

w6.....	Mugwort.....	absinthium, Artemisia annua.
w7.....	Marguerite, ox-eye daisy.	Artemisia vulgaris. Chrysanthemum leucanthemum.
w8.....	Dandelion.....	Taraxacum vulgare, Taraxacum officinale.
w9.....	Plantain (English), Ribwort.	Plantago lanceolata.
w10.....	Goosefoot, lamb's quarters.	Chenopodium album.
w11.....	Saltwort (prickly), Russian thistle.	Salsola kali (Salsola pestifer).
w12.....	Goldenrod.....	Solidago virgaurea (Solidago spp.).
w13.....	Cocklebur, common....	Xanthium commune.
w14.....	Common pigweed (rough pigweed).	Amaranthus retroflexus.
w15.....	Scale, Lenscale.....	Atriplex lentiformis.

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w16.....	Rough marsh elder....	Iva ciliate, Iva annua.
w17.....	Firebush (Kochia)....	Kochia scoparia.
w18.....	Sheep sorrel.....	Rumex acetosella.
w19.....	Wall pellitory.....	Parietaria officinalis.
w20.....	Nettle (Common stinging nettle).	Urtica dioica.
w21.....	Wall pellitory.....	Parietaria judaica.
w22.....	Japanese hop (careless weed).	Humulus japonicas (Humulus scandens).
w23.....	Yellow dock, Yellow dockweed.	Rumex crispus.
w24.....	Spiny pigweed.....	Amaranthus spinosus.
w27.....	Carnation.....	Dianthus spp.
w28.....	Rose.....	Rosa rugosa.
w33.....	Clover.....	Trifolium pratense.
w35.....	Mexican tea.....	Chenopodium ambrosioides.
w36.....	Rabbit bush.....	Ambrosia deltoidea (Franseria deltoides).
w37.....	Salt bush, annual....	Atriplex wrightii.
w39.....	Water hemp, Western..	Amaranthus rudis (Acnida tamariscina).
w41.....	Burrobrush.....	Hymenoclea salsola.
w42.....	Poverty weed.....	
w43.....	Common sagebrush.....	Artemisia tridentata.
w45.....	Alfalfa.....	Medicago sativa.
w46.....	Dog fennel.....	Eupatorium capillifolium.
w53.....	Geranium.....	Geranium spp.
w67.....	Groundsel bush.....	Baccharis halimifolia.
w69.....	Iodine bush.....	Allenrolfea occidentalis.
w70.....	Ragweed, slender....	Ambrosia confertiflora.
w75.....	Wing scale (wingscale).	Atriplex canescens.
w82.....	Careless weed.....	Amaranthus palmeri, Amaranthus hybridus.
w90.....	Japanese hop.....	Humulus japonicas (Humulus scandens).
w203.....	Rape (rape pollen)...	Brassica napus.
w204.....	Sunflower.....	Helianthus annuus.
w206.....	Camomile.....	Matricaria chamomilla.
w207.....	Lupin.....	Lupinus spp.
w210.....	Sugar-beet.....	Beta vulgaris.
w211.....	Par j 2.0101.....	Parietaria judaica.
w231.....	Art v 1.....	Artemisia vulgaris (Mugwort).
w232.....	Sal k 1.....	Salsola kali.
w233.....	Art v 3.....	Artemisa vulgaris (LTP, Mugwort).

w234.....	Pla l 1.....	Plantago lanceolata.
w235.....	Che a l.0101.....	Chenopodium album.
w236.....	Mer a l.0101.....	Mercurialis annua.
a753.....	Art v l.....	Artemisia vulgaris (Mugwort weed).

Tree Pollens

t1.....	Box-elder (Maple)....	Acer negundo, Acer saccharum.
t2.....	Gray alder, speckled alder (alder).	Alnus incana.
t4.....	Hazel, hazelnut.....	Corylus avellana, Corylus americana.
t5.....	American beech (beech).	Fagus grandifolia (Fagus americana).
t6.....	Mountain juniper, Mountain cedar.	Juniperus ashei (Juniperus sabinoides).
t8.....	Elm.....	Ulmus americana.
t9.....	Olive.....	Olea europaea.
t10.....	Walnut.....	Juglans californica, Juglans nigra.
t11.....	Maple leaf sycamore, London plane, Plane tree.	Platanus acerifolia.
t61.....	Sycamore.....	Platanus occidentalis.
t12.....	Willow.....	Salix caprea, Salix nigra.
t14.....	Cottonwood (Eastern Cottonwood/Black Cottonwood).	Populus deltoides.
t15.....	White ash.....	Fraxinus americana.
t16.....	White pine.....	Pinus strobus.
t18.....	Eucalyptus, gum-tree.	Eucalyptus globulus (Eucalyptus spp.).
t19/t26.....	Acacia.....	Acacia longifolia (Acacia spp.).
t20.....	Mesquite.....	Prosopis glandulosa/ Prosopis juliflora.
t21.....	Melaleuca, cajeput tree.	Melaleuca quincunervia (Melaleuca leucadendron).
t22.....	Pecan, hickory.....	Carya illinoensis (Carya pecan).
t23.....	Italian/Mediterranean/ funeral cypress.	Cupressus sempervirens.
t24.....	Japanese cypress.....	Chamaecyparis obtusa (Chamaecyparis spp.).
t25.....	Ash.....	Fraxinus excelsior.
t27.....	Maple, red.....	Acer rubrum.
t29.....	Acacia.....	Acacia spp.
t30.....	Birch, white.....	Betula populifolia.

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t32.....	Willow, black.....	Salix nigra.
t33.....	Ash, Arizona.....	Fraxinus velutina.
t35.....	Cedar, salt.....	Tamarix gallica.
t37.....	Bald cypress (white bald cypress).	Taxodium distichum.
t38.....	Elm, Chinese/Siberian	Ulmus pumila.
t40.....	Hazelnut tree.....	Corylus americana.
t41.....	White hickory.....	Carya alba (Carya tomentosa).
t42.....	Oak, red.....	Quercus rubra.
t43.....	Loblolly pine.....	Pinus taeda.
t44.....	Hackberry.....	Celtis occidentalis.
t45.....	Cedar elm.....	Ulmus crassifolia.
t47.....	Juniper, one seed....	Juniperus monosperma.
t48.....	Pine, lodgepole.....	Pinus contorta.
t49.....	Pine, ponderosa.....	Pinus ponderosa.
t50.....	Beech, European.....	Fagus sylvatica.
t51.....	Tree of Heaven.....	Ailanthus altissima.
t52.....	Western white pine...	Pinus monticola.
t54.....	Russian olive.....	Elaeagnus angustifolia.
t55.....	Scotch broom.....	Cytisus scoparius.
t56.....	Bayberry.....	Myrica cerifera.

t57.....	Red cedar.....	Juniperus virginiana.
t60.....	Western juniper.....	Juniperus occidentalis.
t61.....	Sycamore.....	Platanus occidentalis.
t70.....	Mulberry (white mulberry).	Morus alba.
t71.....	Red mulberry.....	Morus rubra.
t72.....	Queen palm.....	Arecastrum romanzoffiamon.
t73.....	Australian pine.....	Casuarina equisetifolia.
t77.....	Oak mix (red, white, black).	Quercus spp.
t80.....	Japanese cypress.....	Chamaecyparis obtusa.
t81.....	Japanese alder.....	Alnus japonica.
t83.....	Mango tree.....	Mangifera indica.
t90.....	Walnut, black.....	Juglans nigra.
t96.....	Poplar, white (poplar).	Populus alba.
t103/t218.....	Virginia live oak (live oak).	Quercus virginiana.
t105.....	Pepper tree.....	Schinus molle.
t110.....	Orange tree.....	Citrus sinensis.
t201.....	Spruce, Norway spruce	Picea abies (Picea excelsa).
t202.....	Alder, smooth.....	Alnus incana spp. Rugosa (Alnus rugosa).
t203.....	Horse chestnut.....	Aesculus hippocastanum.
t205.....	Elder.....	Sambucus nigra.
t206.....	Chestnut.....	Castanea sativa.
t207.....	Douglas fir.....	Pseudotsuga menziesii (Pseudotsuga taxifolia).
t208.....	Linden.....	Tilia cordata.
t209.....	Horn beam.....	Carpinus betulus.
t210.....	Privet.....	Ligustrum vulgare.
t211.....	Sweet gum.....	Liquidambar styraciflua.
t212.....	Cedar.....	Libocedrus decurrens.
t213.....	Pine.....	Pinus radiata.
t214.....	Date palm.....	Phoenix canariensis.
t215.....	Lilac.....	Syringa vulgaris.
t217.....	Pepper tree.....	Schinus molle.
t217.....	Red alder.....	Alnus rubra.
t218.....	Virginia live oak....	Quercus virginiana.
t218.....	Bayberry (bayberry/ sweet gale).	Myrica gale.
t219.....	Palo verde.....	Cercidium floridum.
t219.....	Red cedar.....	Juniperus virginiana.
t220.....	Bet v 4.....	Betula verrucosa (Birch).
t221.....	Bet v 2.0101, Bet v 4	Betula verrucosa (Birch).
t222.....	Cypress (Arizona cypress).	Cupressus arizonica.
t223.....	Oil palm.....	Elaeis guineensis.
t224.....	Ole e 1.....	Olea europaea.
t225.....	Bet v 6.....	Betula verrucosa (Birch).
t226.....	Cup a 1.....	Cupressus arizonica.
t227.....	Ole e 7.....	Olea Europaea.
t228.....	Aspen, quaking.....	Populus tremuloides.
t229.....	Eastern hemlock.....	Tsuga canadensis.
t230.....	Redwood (sequoia)....	Sequoia sempervirens.
t232.....	Pussy willow.....	Salix discolor.
t240.....	Ole e 9.0101.....	Olea Europaea.
t241.....	Pla a 1.0101.....	Platanus acerifolia.

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t242.....	Pla a 2.....	Platanus acerifolia.
t243.....	Pla a 3.0101.....	Platanus acerifolia.
t244.....	Cor a 1.0103.....	Corylus avellana.
t245.....	Aln g 1.0101.....	Alnus glutinosa.

t246.....	Cry j 1.....	Cryptomeria japonica.
t280.....	Locust tree.....	Robinia pseudoacacia.
t401.....	Brazilian peppertree.	Schinus terebinthifolius.
t402.....	Mastic tree.....	Pistacia lentiscus.
t404.....	Tree of heaven.....	Ailanthus altissima.
t406.....	Date palm.....	Phoenix dactylifera.
a482.....	Ole e 1.....	Olea europaea (Olive Oil).

Mites

d207.....	Blo t 5.0101.....	Blomia tropicalis.
d208.....	Lep d 2.0101.....	Lepidoglyphus destructor.

Microorganisms, Molds, Yeast

m1.....	Penicillium chrysogenum (Penicillium notatum).	Penicillium chrysogenum (Penicillium notatum).
m2.....	Cladosporium herbarum (Hormodendrum).	Cladosporium herbarum (Hormodendrum).
m3.....	Aspergillus fumigatus	Aspergillus fumigatus.
m4.....	Mucor racemosus.....	Mucor racemosus.
m5.....	Candida albicans.....	Candida albicans.
m7.....	Botrytis cinerea.....	Botrytis cinerea.
m8.....	Drechslera halodes (Setomelanomma rostrata, Helminthosporium halodes, Helminthosporium interseminatum).	Drechslera halodes (Setomelanomma rostrata, Helminthosporium halodes).
m9.....	Fusarium moniliforme (Fusarium proliferatum).	Fusarium moniliforme (Fusarium proliferatum).
m10.....	Stemphylium botryosum	Stemphylium herbarum (Stemphylium botryosum).
m11.....	Rhizopus nigricans...	Rhizopus nigricans.
m12.....	Aureobasidium pullulans.	Aureobasidium pullulans.
m13.....	Phoma betae.....	Phoma betae.
m14.....	Epicoccum purpurascens.	Epicoccum purpurascens (Epicoccum nigrum).
m15.....	Trichoderma viride...	Trichoderma viride.
m16.....	Curvularia lunata....	Curvularia lunata Curvularia specifera (K923044).
m17.....	Cladosporium fulvum..	Cladosporium fulvum.
m18.....	Fusarium culmorum....	Fusarium culmorum.
m19.....	Aspergillus versicolor.	Aspergillus versicolor.
m20.....	Mucor mucedo.....	Mucor mucedo.
m21.....	Aspergillus clavatus.	Aspergillus clavatus.
m22.....	Micropolyspora faeni.	Saccharopolyspora rectivirgula (Micropolyspora faeni).
m23.....	Thermoactinomyces vulgaris.	Thermoactinomyces vulgaris.
m24.....	Stachybotrys atra....	Stachybotrys chartarum (Stachybotrys atra).
m24.....	Paecilomyces spp.....	Paecilomyces spp.
m25.....	Aspergillus versicolor.	Aspergillus versicolor.
m25.....	Penicillium brevicompactum.	Penicillium brevicompactum.
m26.....	Cladosporium cladosporioides.	Cladosporium cladosporioides.
m26.....	Penicillium citrinum.	Penicillium citrinum.
m27.....	Penicillium spp.....	Penicillium spp.

m29.....	Aspergillus repens...	Aspergillus repens.
m30.....	Penicillium roqueforti.	Penicillium roqueforti.
m32.....	Cladosporium cladosporioides.	Cladosporium cladosporioides.
m34.....	Serpula lacrymans....	Serpula lacrymans.
m36.....	Aspergillus terreus..	Aspergillus terreus.
m37.....	Trichophyton mentagrophytes.	Trichophyton mentagrophytes.
m40.....	Aspergillus amstelodami.	Aspergillus amstelodami.
m43.....	Saccharomyces carlsberg.	Saccharomyces carlsbergensis.
m44.....	Saccharomyces cerevisiae.	Saccharomyces cerevisiae.
m45.....	Hormodendrum hordei..	Hormodendrum hordei.
m46.....	Bipolaris spicifera..	Bipolaris spicifera.
m47.....	Aspergillus nidulans.	Aspergillus nidulans.
m48.....	Aspergillus oryzae...	Aspergillus oryzae.
m49.....	Fusarium oxysporum...	Fusarium oxysporum.
m50.....	Micropolyspora faeni.	Saccharopolyspora rectivirgula (Micropolyspora faeni).
m51.....	Thermoactinomyces vulgaris.	Thermoactinomyces vulgaris.
m53.....	Microspora canis.....	Microsporium canis (Microspora canis).
m54.....	Aspergillus flavus...	Aspergillus flavus.
m63.....	Helminthosporium intersemin.	Helminthosporium intersemin.
m66.....	Mucor plumbeus.....	Mucor plumbeus.
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m67.....	Mycogone.....	Mycogone perniciosa.
m68.....	Nigrospora oryzae....	Nigrospora oryzae.
m69.....	Rhodotorula.....	Rhodotorula rubra (Rhodotorula mucilaginoso).
m70.....	Malassezia furfur (Pityrosporum orbiculare).	Malassezia furfur (Pityrosporum orbiculare).
m71.....	Spondylocladium.....	Spondylocladium spp.
m72.....	Epidermophyton.....	Epidermophyton floccosum.
m73.....	Epicoccum nigrum.....	Epicoccum purpurascens (Epicoccum nigrum).
m80.....	Staphylococcal enterotoxin A (Sta a SEA).	Staphylococcus aureus.
m80.....	Helminthosporium spp.	Helminthosporium spp.
m81.....	Staphylococcal enterotoxin B (Sta a SEB).	Staphylococcus aureus.
m88.....	Stemphylium solani...	Stemphylium solani.
m93.....	Gliocladium fimbriatum.	Gliocladium fimbriatum.
m94.....	Phycomyces blakesleeanus.	Phycomyces blakesleeanus.
m201.....	Tilletia tritici (Ustilago nuda, Ustilago tritici) (Barley smut).	Tilletia tritici (Ustilago nuda, Ustilago tritici).
m202.....	Acremonium kiliense (Cephalosporium acremonium).	Acremonium kiliense (Cephalosporium acremonium).
m203.....	Trichosporon pullulans.	Trichosporon pullulans.
m204.....	Ulocladium chartarum.	Ulocladium chartarum.
m205.....	Trichophyton rubrum..	Trichophyton rubrum.
m207.....	Aspergillus niger....	Aspergillus niger.
m208.....	Chaetomium globosum..	Chaetomium globosum.
m209.....	Penicillium frequentans.	Penicillium glabrum (Penicillium frequentans).
m209.....	Stachybotrys chartarum.	Stachybotrys chartarum (Stachybotrys

m210.....	Trichophyton mentagrophytes var. goetzii.	Trichophyton mentagrophytes var. goetzii.
m211.....	Trichophyton mentagrophytes var. interdigitale.	Trichophyton mentagrophytes var. interdigitale.
m211.....	Oat smut.....	Ustilago avenae.
m212.....	Micropolyspora faeni.	Saccharopolyspora rectivirgula (Micropolyspora faeni).
m212.....	Geotrichum candidum..	Geotrichum candidum.
m213.....	Bermuda grass smut...	Ustilago cynodontis.
m214.....	Johnson grass smut...	Sphacelotheca cruenta.
m215.....	Corn smut.....	Ustilago maydis.
m218.....	Asp f 1.0101.....	Aspergillus fumigatus.
a3050.....	Asp r 1.....	Aspergillus restrictus.
m219.....	Asp f 2.....	Aspergillus fumigatus.
m220.....	Asp f 3.0101.....	Aspergillus fumigatus.
m221.....	Asp f 4.....	Aspergillus fumigatus.
m222.....	Asp f 6.0101.....	Aspergillus fumigatus.
m223.....	Staphylococcal enterotoxin C (Sta a SEC).	Staphylococcus aureus.
m224.....	Staphylococcal enterotoxin D (Sta a SED).	Staphylococcus aureus.
m226.....	Staphylococcal enterotoxin TSST (Sta a TSST).	Staphylococcus aureus.
m227.....	Malassezia spp. (Pityrosporum spp.).	Malassezia spp. (Pityrosporum spp.).
m228.....	Aspergillus flavus.
m229.....	Alt a 1.0101.....	Alternaria alternata (Alternaria tenuis).
m230.....	Alt a 6.0101.....	Alternaria alternata (Alternaria tenuis).
m231.....	Cla h 8.0101.....	Cladosporium herbarum (Hormodendrum).
m300.....	Eurotium spp.....	Eurotium spp.
m304.....	Aspergillus oryzae...	Aspergillus oryzae.
m305.....	Penicillium brevicompactum.	Penicillium brevicompactum.
m309.....	Aspergillus terreus..	Aspergillus terreus.
m310.....	Aspergillus nidulans.	Aspergillus nidulans.
m311.....	Aspergillus flavus...	Aspergillus flavus.
m312.....	Aspergillus clavatus.	Aspergillus clavatus.

 Epidermal & Animal

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

e78.....	Budgerigar feathers..	undulatus. Melopsittacus undulatus.
e79.....	Budgerigar serum proteins.	Melopsittacus undulatus.
e80.....	Goat epithelium.....	Capra hircus.
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e81.....	Sheep epithelium.....	Ovis aries (Ovis spp.).
e82.....	Rabbit epithelium....	Oryctolagus cuniculus (Oryctolagus spp.).
e83.....	Swine epithelium.....	Sus scrofa (Sus scrofa domesticus; Sus spp.).
e84.....	Hamster epithelium...	Cricetus cricetus, Mesocricetus auratus, and Phodopus sungorus.
e85.....	Chicken feathers.....	Gallus domesticus (Gallus gallus domesticus; Gallus spp.).
e86.....	Duck feathers.....	Anas platyrhynchos.
e87.....	Rat epithelium, serum proteins, and urine proteins.	Rattus norvegicus Rattus rattus.
e88.....	Mouse epithelium, serum proteins, and urine proteins (mouse).	Mus musculus (Mus spp.).
e89.....	Turkey feathers.....	Meleagris gallopavo.
e90.....	Budgerigar serum proteins, feathers, and droppings.	Melopsittacus undulatus.
e91.....	Pigeon serum proteins, feathers, and droppings.	Streptopelia roseogrisea Psittacidae spp.
e92.....	Parrot serum proteins, feathers, and droppings.	Ara spp.
e93.....	Pigeon serum proteins	Streptopelia roseogrisea.
e94.....	Fel d 1.0101.....	Felis domesticus.
a345.....	Fel d 1.....	Felis domesticus.
e98.....	Parrot droppings.....	Psittacoidea spp.
e101.....	Can f 1.0101.....	Canis familiaris (Canis domesticus).
a174.....	Can f 1.....	Canis familiaris (Canis domesticus).
e102.....	Can f 2.0101.....	Canis familiaris (Canis domesticus).
e196.....	Parakeet feathers....	Nymphicus hollandicus.
e197.....	Parakeet droppings...	Nymphicus hollandicus.
e198.....	Parakeet serum.....	Nymphicus hollandicus.
e199.....	Canary bird serum....	Serinus canarius.
e200.....	Canary bird droppings	Serinus canarius.
e201.....	Canary bird feathers (Canary feathers).	Serinus canarius.
e202.....	Reindeer epithelium..	Rangifer tarandus.
e203.....	Mink epithelium.....	Mustela spp.
e204.....	Bos d 6.....	Bos domesticus (Bos taurus; Bos spp.).
e205.....	Horse, serum proteins	Equus caballus (Equus spp.).
e206.....	Rabbit, serum proteins.	Oryctolagus cuniculus (Oryctolagus spp.).
e208.....	Chinchilla epithelium	Chinchilla laniger.
e209.....	Gerbil epithelium....	Meriones unguiculatus.
e210.....	Fox epithelium.....	Vulpes vulpes.
e211.....	Rabbit, urine proteins.	Oryctolagus cuniculus (Oryctolagus spp.).
e212.....	Swine, urine proteins	Sus scrofa (Sus scrofa domesticus; Sus spp.).

e213.....	Parrot feathers.....	Ara spp.
e214.....	Finch feathers.....	Lonchura domestica.
e215.....	Pigeon feathers.....	Streptopelia roseogrisea (Streptopelia spp.), Columbia spp.
e216.....	Deer epithelium.....	Dama dama.
e217.....	Ferret epithelium....	Mustela putorius.
e218.....	Chicken droppings....	Gallus domesticus (Gallus gallus domesticus; Gallus spp.).
e219.....	Chicken, serum proteins.	Gallus domesticus (Gallus gallus domesticus; Gallus spp.).
e220.....	Fel d 2, Cat serum albumin.	Felis domesticus.
e221.....	Can f 3.....	Canis familiaris (Canis domesticus) (Dog serum albumin).
e222.....	Swine serum albumin (Sus s PSA).	Sus scrofa (Sus scrofa domesticus; Sus spp.).
e225.....	Lovebird feathers....	Psittacoidea agapomis.
e226.....	Can f 5.0101.....	Canis familiaris.
e227.....	Equ c 1.0101.....	Equus caballus.
e228.....	Fel d 4.0101.....	Felis domesticus.
e230.....	Equ c 3.....	Equus caballus.
e231.....	Mus m 1.....	Mus musculus.

Food

f9.....	Rice.....	Oryza sativa.
f12.....	Pea (green pea).....	Pisum sativum.
f15.....	White bean.....	Phaseolus vulgaris.
f19.....	Cayenne pepper.....	Capsicum frutescens, (Capsicum annum).
f21.....	Sugar cane.....	Saccharum officinarum.
f22.....	Raspberry.....	Rubus idaeus.
f26.....	Pork.....	Sus scrofa (Sus scrofa domesticus; Sus spp.).
f29.....	Watermelon.....	Citrullus lanatus (Citrullus vulgaris).
f31.....	Carrot.....	Daucus carota.
f32.....	Oyster mushroom.....	Pleurotus ostreatus.

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f33.....	Orange.....	Citrus sinensis.
f35.....	Potato.....	Solanum tuberosum.
f43.....	Mother's milk.....	Homo sapiens.
f44.....	Strawberry.....	Fragaria vesca (Fragaria spp.).
f45.....	Yeast, baker's.....	Saccharomyces cerevisiae.
f46.....	Pepper, Red.....	Capsicum annum.
f47.....	Garlic.....	Allium sativum.
f48.....	Onion.....	Allium cepa.
f49.....	Apple.....	Malus x domestica (Malus spp.).
f51.....	Bamboo shoot.....	Phyllostachys pubescens.
f52.....	Cacao/chocolate.....	Theobroma cacao.
f54.....	Sweet potato.....	Ipomoea batatas.
f55.....	Common millet.....	Panicum miliaceum.
f56.....	Foxtail millet.....	Setaria italica.
f57.....	Japanese millet.....	Echinochloa crus- galli.
f58.....	Pacific squid.....	Todarodes pacificus.
f59.....	Octopus.....	Octopus vulgaris (Octopus spp.).
f63.....	Kefir.....	NA.
f67.....	Parmesan cheese.....	NA.
f81.....	Cheese, cheddar type.	NA.
f82.....	Cheese, mold type....	NA.
f83.....	Chicken.....	Gallus domesticus

		(Gallus gallus domesticus; Gallus spp.).
f86.....	Parsley.....	Petroselinum crispum.
f87.....	Melon.....	Cucumis melo Cucumis melo + Citrullus lanatus.
f88.....	Mutton (lamb).....	Ovis aries (Ovis spp.).
f90.....	Malt.....	Hordeum vulgare.
f92.....	Banana.....	Musa spp.
f93.....	Cacao.....	Theobroma cacao.
f94.....	Pear.....	Pyrus communis (Pyrus spp.).
f97.....	Yam.....	Dioscorea spp., Dioscorea opposita.
f97.....	Chamomile tea.....	Matricaria chamomilla.
f98.....	Gliadin.....	Triticum aestivum (Triticum spp.).
f102.....	Cantaloupe.....	Cucumis melo var. cantalupensis.
f105.....	Chocolate.....	Theobroma cacao.
f109.....	Cottonseed.....	Gossypium hirsutum.
f110.....	Giant radish.....	Raphanus sativus.
f118.....	Zucchini.....	Cucurbita pepo.
f119.....	Radish.....	Raphanus sativus.
f120.....	Venison.....	Capreolus capeolus.
f121.....	Pinto bean.....	Phaseolus vulgaris.
f122.....	Cheese, American.....	NA.
f127.....	Black-eyed pea.....	Vigna unguiculata.
f131.....	Black Olive.....	Olea europaea.
f136.....	Red beet.....	Beta vulgaris var. conditiva.
f139.....	Goat's Cheese.....	Capra aegagrus.
f140.....	Bran.....	NA.
f141.....	Corn (vegetables)....	Zea mays.
f152.....	Green bell pepper....	Capsicum annuum.
f155.....	Brewer's yeast.....	Saccharomyces carlsbergensis.
f157.....	Duck.....	Anas domesticus.
f158.....	Goose.....	Anser anser.
f160.....	Camembert cheese.....	NA.
f162.....	Nectarine.....	Prunus persica var. nucipersica.
f163.....	Kohlrabi.....	Brassica oleracea var. gongylodes.
f65.....	Perch.....
f166.....	Leek.....	Allium porrum.
f170.....	Cheese (Switzerland) (Swiss cheese).	NA.
f174.....	Fig.....	Ficus carica.
f177.....	Cranberry.....	Vaccinium macrocarpon.
f179.....	Raisin.....	Vitis spp.
f182.....	Lima bean.....	Phaseolus lunatus.
f198.....	Flaxseed (bruised grain).	Linum usitatissimum.
f199.....	Untreated native milk	Bos domesticus (Bos taurus; Bos spp.).
f208.....	Lemon.....	Citrus limon.
f209.....	Grapefruit.....	Citrus paradisi.
f210.....	Pineapple.....	Ananas comosus.
f211.....	Blackberry.....	Rubus fruticosus.
f212.....	Mushroom (champignon)	Agaricus hortensis (Agaricus spp.).
f213.....	Rabbit.....	Oryctolagus cuniculus (Oryctolagus spp.).
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f214.....	Spinach.....	Spinacia oleracea.
f215.....	Lettuce.....	Lactuca sativa.
f216.....	Cabbage.....	Brassica oleracea var. capitata.
f217.....	Brussels sprouts.....	Brassica oleracea var. gem.
f218.....	Paprika, sweet pepper	Capsicum annuum.
f219.....	Fennel seed.....	Foeniculum vulgare.
f219.....	Sage.....	Salvia officinalis.
f220.....	Cinnamon.....	Cinnamomum spp.

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

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f300.....	Pinto bean.....	Phaseolus spp.
f301.....	Persimmon (kaki fruit, sharon).	Diospyros kaki.
f302.....	Mandarin (tangerine, clementine, satsumas).	Citrus reticulata.
f305.....	Fenugreek.....	Trigonella foenum- graecum.
f306.....	Lime.....	Citrus aurantifolia.
f307.....	Hake.....	Merluccius merluccius.
f308.....	Sardine (pilchard)...	Sardina pilchardus.
f310.....	Blue vetch.....	Lathyrus sativus.
f311.....	Megrim.....	Lepidorhombus whiffiagonis.
f315.....	Green bean.....	Phaseolus vulgaris.
f316.....	Rape seed.....	Brassica napus.
f317.....	Coriander.....	Coriandrum sativum.
f318.....	Jack fruit.....	Artocarpus heterophyllus.
f319.....	Beetroot.....	Beta vulgaris.
f320.....	Crayfish.....	Astacus astacus.
f321.....	Horse meat.....	Equus caballus (Equus spp.).
f322.....	Red currant.....	Ribes sylvestre.
f324.....	Hop (fruit cone)....	Humulus lupulus.
f325.....	Saffron.....	Colchicum autumnale.
f328.....	Fig.....	Ficus carica.
f329.....	Watermelon.....	Citrullus lanatus.
f330.....	Rose hip.....	Rosa spp.
f331.....	Saffron.....	Crocus sativus.
f332.....	Mint.....	Mentha piperita.
f333.....	Linseed.....	Linum usitatissimum.
f336.....	Jujube.....	Ziziphus jujuba.
f336.....	Wine vinegar.....	Vitis vinifera (Vitis spp.).
f337.....	Sole.....	Solea solea.
f337.....	English sole.....	Parophrys vetulus.
f338.....	Wine, white.....	Vitis vinifera (Vitis spp.).
f339.....	Allspice.....	Pimenta dioica.
f339.....	Wine, red.....	Vitis vinifera (Vitis spp.).
f341.....	Cranberry.....	Vaccinium oxycoccus, Vaccinium macrocarpon.
f342.....	Olive (black, fresh).	Olea europaea.
f343.....	Raspberry.....	Rubus idaeus.
f344.....	Sage.....	Salvia officinalis.
f346.....	Chives.....	Allium schoenoprasum.
f347.....	Quinoa.....	Chenopodium quinoa.
f348.....	Litchi.....	Litchi chinensis.
f349.....	Chum salmon roe.....	Oncorhynchus keta.
f358.....	Artichoke.....	Cynara scolymus.
f360.....	Yogurt.....	NA.
f368.....	Black bass.....	Micropterus dolomieu (Micropterus dolomieu).
f374.....	Karaya gum.....	Sterculia urens.
f375.....	Horseradish.....	Armoracia rusticana.
f377.....	Maple syrup.....	NA.
f379.....	Okra.....	Abelmoschus esculentus.
f382.....	Beet, sugar.....	Beta vulgaris var. altissima.
f401.....	Loquat.....	Eriobotrya japonica.
f402.....	Fig.....	Ficus carica.
f403.....	Brewer's yeast.....	Saccharomyces cerevisiae.
f405.....	Mint.....	Mentha spp.
f406.....	Arugula.....	Eruca vesicaria.

House Dust

h1.....	Greer Labs., Inc.....	NA.
h2.....	Hollister-Stier Labs.	NA.
h6.....	Japan.....	NA.

Venoms & Insects

i7.....	Midge.....	Chironomus yoshimatsui.
i8.....	Moth.....	Bombyx mori, Heterocera spp.
i47.....	Water flea.....	Daphnia spp.
i49.....	Deer fly.....	Chrysops spp.
i51.....	Black ant.....	Camponotus pennsylvanicus.
i54.....	Flea mix (dog/cat), common flea.	Ctenocephalides spp.
i71.....	Mosquito.....	Aedes communis, Aedes spp. and Culex spp.
i72.....	Green nimitti.....	Cladotanytarsus lewisi.
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i73.....	Blood worm.....	Chironomus thummi, Chironomusri parius, Chironomus spp.
i75.....	European hornet.....	Vespa crabro.
i76.....	Berlin beetle.....	Trogoderma angustum.
i77.....	European paper wasp..	Polistes dominulus.
i78.....	Fly.....	Musca domestica.
i80.....	Bumblebee.....	Bombus pennsylvanicus.
i201.....	Horse bot fly.....	Gasterophilus intestinalis.
i202.....	Grain weevil.....	Sitophilus granarius.
i203.....	Mediterranean flour moth.	Ephestia kuehniella (Anagasta kuehniella).
i204.....	Horse fly.....	Tabanus spp.
i205.....	Bumblebee.....	Bombus terrestris.
i208.....	Api m 1.0101.....	Apis mellifera.
a45.....	Api m 1.....	Apis mellifera.
i209.....	Ves v 5.0101.....	Vespula vulgaris.
a670.....	Ves v 5.....	Vespula vulgaris.
i210.....	Pol d 5.0101.....	Polistes dominulus.
i211.....	Ves v 1.0101.....	Vespula vulgaris.
i213.....	Api m 4.....	Apis mellifera.
i214.....	Api m 2.....	Apis mellifera.
i215.....	Api m 3.....	Apis mellifera.
i216.....	Api m 5.....	Apis mellifera.
i217.....	Api m 10.....	Apis mellifera.
i220.....	Bla g 1.0101.....	Blattella germanica.
i221.....	Bla g 2.0101.....	Blattella germanica.
i222.....	Bla g 5.0101.....	Blattella germanica.
i223.....	Bla g 7.....	Blattella germanica.
a46.....	Api m 2.....	Apis mellifera.

Miscellaneous

o1.....	Cotton, crude fibers.	Gossypium spp.
o3.....	Cotton (treated).....	Gossypium spp.
o70.....	Seminal fluid.....	Homo sapiens.
o71.....	Staphylococcus aureus	Staphylococcus aureus.
o72.....	Pichia pastoris crude extract customer specific.	Pichia pastoris.
o72.....	Sperm-sediment.....	Homo sapiens.
o73.....	Pichia pastoris crude extr. vector customer specific.	Pichia pastoris.
o74.....	Pichia pastoris with vector customer specific.	Pichia pastoris.
o201.....	Tobacco leaf, tobacco dust.	Nicotiana tabacum.
o202.....	Artemia salina, fish feed.	Artemia salina.
o203.....	Tetramin, fish feed..	NA.
o207.....	Daphnia, fish feed...	Daphnia spp.
o211.....	Mealworm.....	Tenebrio molitor.
o212.....	Streptavidin.....	Streptomyces avidini.
o213.....	MBP (maltose binding protein).	Escherichia coli.
o214.....	CCD; MUXF3 from	Ananas comosus.

o72.....	bromelain. Enterotoxin A (Sta a SEA).	Staphylococcus aureus.
o73.....	Enterotoxin B (Sta a SEB).	Staphylococcus aureus.

Parasites

p1.....	Ascaris.....	Ascaris suum.
p2.....	Echinococcus.....	Echinococcus granulosus.
p3.....	Schistosoma.....	Schistosoma mansoni.
p4.....	Anisakis (Herring Worm).	Anisakis simplex (Anisakis spp.).
p5.....	Toxocara canis.....	Toxocara canis.
p10.....	Ani s 3.0101.....	Anisakis simplex (Anisakis spp.).
p11.....	Ani s 1.....	Anisakis simplex (Anisakis spp.).

Occupational

k4.....	Threshing dust.....	NA.
k5.....	Flax.....	NA.
k7.....	Hay Dust.....	NA.
k8.....	Hop (hops).....	Humulus lupulus.
k12.....	Grain mill dust.....	NA.
k14.....	Kapok.....	NA.
k20.....	Sheep's wool (treated) (wool).	Ovis aries (Ovis spp.).
k21.....	Sheep's wool (Untreated).	Ovis aries (Ovis spp.).

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k23.....	Straw Dust.....	NA.
k33.....	Oak.....	NA.
k70.....	Green coffee bean....	Coffea spp.
k71.....	Castor bean.....	Ricinus communis.
k72.....	Ispaghula.....	Plantago psyllium/ Plantago ovata.
k73.....	Silk waste.....	NA.
k74.....	Silk.....	Bombyx mori.
k75.....	Isocyanate TDI (Toluene diisocyanate).	NA.
k76.....	Isocyanate MDI (Diphenylmethane diisocyanate).	NA.
k77.....	Isocyanate HDI (Hexamethylen diisocyanate).	NA.
k78.....	Ethylene oxide.....	NA.
k79.....	Phthalic anhydride...	NA.
k80.....	Formaldehyde/Formalin	NA.
k81.....	Ficus.....	Ficus benjamina (Ficus spp.).
k83.....	Cotton seed.....	Gossypium hirsutum.
k84.....	Sunflower seed.....	Helianthus annuus.
k85.....	Chloramin T.....	NA.
k86.....	Trimellitic anhydride, TMA.	NA.
k87.....	Asp o 21, alpha- amylase.	Aspergillus oryzae.
k89.....	Orris root.....	Iris florentina.
k99.....	HSA (Human Serum Albumin) (Hom s HSA).	Homo sapiens.
k201.....	Car p 1, Papain.....	Carica papaya.
k202.....	Ana c 2, Bromelain...	Ananas comosus.
k204.....	Maxatase.....	Bacillus licheniformis.
k205.....	Alcalase.....	Bacillus spp.
k206.....	Savinase, Protease 1 (Bac l Subtilisin).	Bacillus spp.
k208.....	Gal d 4, Lysozyme....	Gallus domesticus (Gallus gallus domesticus; Gallus spp.).
k209.....	Hexahydroptalic anhydrid.	NA.
k210.....	Maleic anhydride....	NA.
k211.....	Methyltetrahydroptal ic anhydrid.	NA.

k212.....	Abachi wood dust.....	Triplochiton scleroxylon.
k213.....	Pepsin (Sus s Pepsin)	Sus scrofa (Sus scrofa domesticus; Sus spp.).
k213.....	TCPA.....	NA.
k214.....	Bougainvillea.....	Bougainvillea spp.
k225.....	Horse radish peroxidase (Arm r HRP).	Armoracia rusticana.
k226.....	Ascorbate oxidase (Cuc p ascorbate oxidase).	Cucurbita pepo.
k301.....	Flour dust.....	Triticum spp.
k501.....	Savinase customer specific.	Proprietary knowledge of customer.
k502.....	Lipolase customer specific.	Proprietary knowledge of customer.
k503.....	Termamyl customer specific.	Proprietary knowledge of customer.
k504.....	Clazinase customer specific.	Proprietary knowledge of customer.

V. Reference

The following reference is on display in the 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>.

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 Leslie Kux,
 Associate Commissioner for Policy.
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