Column A—What information is requested?	Column B—Put data specific to the nominated substance
What medical condition(s) is the drug product compounded with the bulk drug substances intended to treat?	Describe the medical condition(s) that the drug product compounded with the bulk drug substances is intended to treat.
Are there other drug products approved by FDA to treat the same medical condition?	List the other approved treatments.
If there are FDA-approved drug products that address the same medical condition, why is there a clinical need for a compounded drug product?	Provide a justification for clinical need, including an estimate of the size of the population that would need the compounded drug.
Are there safety and efficacy data on compounded drugs using the nominated substance?	Provide a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature.
If there is an FDA-approved drug product that includes the bulk drug substance nominated, is it necessary to compound a drug product from the bulk drug substance rather than from the FDA-approved drug product?	Provide an explanation of why it is necessary to compound from the bulk drug substance.
What dosage form(s) will be compounded using the bulk drug substance?	State the dosage form(s).
What strength(s) will be compounded from the nominated substance?	List the strength(s) of the drug product(s) that will be compounded from the nominated substance, or a range of strengths, if known.
What are the anticipated route(s) of administration of the compounded drug product(s)?	List the route(s) of administration of the compounded drug product(s).
Has the bulk drug substance been used previously to compound drug product(s)?	Describe previous uses of the bulk drug substance in compounding.
Is there any other relevant information?	Provide any other information you would like FDA to consider in evaluating the nomination.

In addition to nominating new substances or renominating substances previously nominated without sufficient supporting information, individuals and organizations will be able to comment via the docket established by this notice on substances nominated for the 503B bulks list that have not yet been addressed in a **Federal Register** document proposing substances for the 503B bulks list. Comments may be submitted regarding nominations submitted to both this docket and nominations previously submitted to Docket No. FDA–2013–N–1524. Comments may provide any relevant information about particular bulk drug substances, including that in support of, or in opposition to, the placement of a nominated bulk drug substance on the 503B bulks list. However, comments submitted should not address the 503B bulks list generally or other matters related to the Agency's regulation of compounding. Comments about nominated substances that have been addressed by the Agency in a **Federal Register** document proposing substances for the 503B bulks list should be submitted to the docket for the document in which the substance is addressed.

Please do not submit comments that have already been submitted to other dockets. Such submissions are duplicative and not helpful to the Agency. If comments on particular documents or issues are submitted to this docket rather than the docket specifically opened for the particular document or issue, the comment might not be considered as the specific documents are being finalized and issues considered. FDA will not respond to questions submitted to this docket.

Information in the docket will be publicly available. Therefore, we remind nominators and commenters not to submit personal or confidential information.

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27270 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3455]

Medical Devices; Exemptions From Premarket Notifications; Class II Devices; Autosomal Recessive Carrier Screening Gene Mutation Detection System; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to exempt from the premarket notification requirements autosomal recessive carrier screening gene mutation detection systems, subject to certain limitations. These devices are qualitative in vitro molecular diagnostic systems used for genotyping of clinically relevant variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens intended for prescription use or over-the-counter use. These devices are intended for autosomal recessive disease carrier screening in adults of reproductive age. These devices are not intended for copy number variation, cytogenetic, or biochemical testing. FDA is publishing this notice in order to obtain comments regarding the proposed exemption.

DATES: Submit electronic or written comments by November 27, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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–2015–N–3455 for Medical Devices; Exemptions from Premarket Notifications; Class II Devices; Autosomal Recessive Carrier Screening Gene Mutation Detection System. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a device to submit and obtain FDA clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law the FDA Modernization Act (FDAMA) (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the FD&C Act. Section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Factors FDA May Consider for Exemption

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

III. Proposed Class II Device Exemption

On February 19, 2015, FDA completed its review of a de novo request for classification of the 23andMe Personal Genome Service (PGS) Carrier Screening Test for Bloom Syndrome. FDA classified the 23andMe PGS Carrier Screening Test for Bloom Syndrome, and substantially equivalent devices of this generic type, into class II (special controls) under the generic name ''Autosomal recessive carrier screening gene mutation detection system.'' This type of device is a qualitative in vitro molecular diagnostic system used for genotyping of clinically relevant variants in genomic DNA isolated from human specimens intended for prescription use or over-the-counter use. The device is intended for autosomal recessive disease carrier screening in adults of reproductive age. The device is not intended for copy number variation, cytogenetic, or biochemical testing. Elsewhere in this issue of the **Federal Register**, FDA is publishing an order to codify the classification of the device at 21 CFR 866.5940.

Based on the analysis described in this document, FDA has determined that premarket notification for an autosomal recessive carrier screening gene mutation detection system is not necessary for assurance of the safety and effectiveness of the device, subject to the limitations described in section IV. FDA has assessed the need for 510(k) clearance for an autosomal recessive carrier screening gene mutation detection system against the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) and the January 21, 1998, **Federal Register** notice (63 FR 3142) and has determined that the factors weigh in favor of 510(k) exemption, for the following reasons:

A. History of False or Misleading Claims or of Risks Associated With Inherent Characteristics of the Device

FDA has generally considered whether a type of device has had a significant history of false or misleading claims or of risks associated with inherent characteristics of the device,

such as device design or materials when determining whether a 510(k) exemption is appropriate. Given that autosomal recessive carrier screening gene mutation detection systems were initially classified on February 19, 2015, under the de novo process, a process by which FDA evaluates novel devices anew, FDA has considered other related factors, including: (1) The probable frequency, persistence, cause, and seriousness of such claims or risks; and (2) mitigations of risk provided by the special controls, in combination with general controls.

To demonstrate clinical validity for this type of test, one must define an inheritance pattern of genetic disease and demonstrate the appropriate genetic patterns are present in an informative population that includes affected persons. The nature and level of scientific evidence necessary to establish autosomal recessive inheritance patterns makes it easily discernable whether such evidence establishes clinical validity or not. Thus, the special controls requiring that clinical validity be scientifically established and that evidence supporting such must be publicly posted on the manufacturer's Web site render the probability of false or misleading claims for autosomal recessive inheritance very low. Clinical validity must be well-established in peer reviewed journal articles, authoritative summaries of the literature, and/or professional society recommendations. If there is no professional guideline recommending testing of a certain gene or variant in the indicated population, the manufacturer's Web site must warn that no such recommendation currently exists.

When considering the risks associated with the inherent characteristics of tests of this type, FDA has considered the risks of both false positive and false negative results, as well as the applicable mitigations provided by the special controls, in combination with general controls. The probable risks posed by devices of this type are generally similar regardless of the genetic carrier condition to be detected, as explained in this document.

Autosomal recessive carrier screening is a type of genetic testing performed on people who display no symptoms for a recessive genetic disorder but may be at risk for passing it on to their children if they are detected to be a carrier. A carrier for a genetic disorder has inherited one normal and one abnormal allele for a gene associated with a disorder. Autosomal (non-sex chromosome-related) recessive disorders require that two abnormal copies of a gene, one inherited from each parent, be present in order for the disorder to be manifested. Therefore, to have a child with an autosomal recessive disorder, both parents must be carriers of an abnormal gene copy. When both parents are carriers for the abnormal copy, there is an *a priori* 1 in 4 chance (25 percent) that the child will inherit two abnormal copies of the gene and manifest the specific disease or condition.

FDA believes that the risks posed by false positives are relatively low, and sufficiently mitigated by the applicable special controls, including requirements that establish minimum performance specifications, without the need for premarket notification. Although some autosomal recessive genetic diseases are more common in certain ethnic, racial, or geographically-bounded groups, even in these groups disease frequencies tend to be low. Most autosomal recessive genetic diseases are very rare with frequencies much less than 1 percent in the general population, and the respective carrier frequencies are likewise low in most populations. For reference, sickle cell trait (carrier of sickle cell mutation), which has one of the highest known carrier frequencies, is estimated to occur in about 1 of 13 African Americans, and cystic fibrosis carrier status is estimated to occur in about 1 of 25 Caucasians. Persons outside these groups have lower carrier frequencies for sickle cell and cystic fibrosis carrier status. Other autosomal recessive diseases are rarer and their carrier frequencies are correspondingly lower. Carrier screening is only intended to detect heterozygotes (carriers), so false positive results would only suggest that a person was a carrier of a mutation, and would not contain information that could lead to conclusions of disease for the tested person. Further, no conclusion about an individual's future children could be made given that the carrier status of the child's second parent would need to be known to reach such a conclusion, and even where both parents are truly positive the only conclusion that may be drawn is that the child has a 25 percent likelihood of manifesting the disease. The probability of a couple both receiving false positive carrier results from using a device of this type is vastly smaller than for a single false positive.

In this rare scenario, a couple both receiving false positive results could lead to the couple choosing not to get married or not to have children, or the results could lead to unnecessary fetal testing in current or future pregnancies. Fetal testing may consist of amniocentesis or chorionic villus sampling (CVS), neither of which is risk-free, although other risk factors during pregnancy, including age, often warrant such testing regardless of any carrier screening results. A false positive result for an individual may also potentially lead to adverse psychological effects, particularly if that individual does not fully understand the nature of autosomal recessive disorders (*i.e.,* that both the mother and father must be carriers in order to have a 25 percent chance that their child would have the disorder). FDA believes that the applicable special controls are sufficient to mitigate such risks without the need for premarket review, including: (1) The requirement for over-the-counter test manufacturers to provide users information about how to obtain access to the counseling services of a board-certified clinical molecular geneticist or equivalent, and (2) labeling and comprehension study requirements to help ensure that users are able to understand the limitations and context of the testing prior to ordering.

Similarly, the applicable special controls, including labeling requirements and requirements that establish minimum performance specifications, sufficiently mitigate the risks posed by analytical false negatives for autosomal recessive carrier status without the need for premarket notification. Regardless of analytical accuracy, there exists a risk of a clinical false negative result for many carrier tests because not all clinically relevant mutations are known or tested for; therefore there will be a proportion of carriers who will not be detected. The proportion of people who are true carriers who would be detected by any test is known as the test's ''coverage.'' For many carrier conditions, clinical false negative rate due to ''coverage'' less than 100 percent is likely higher than the false negative rate from analytical failure or random error of a test. The clinical risks associated with false negative results generally occur when only one biological parent is tested and experiences a false negative result, since in that case it is unlikely the other biological parent will be tested. The risk of the false negative would only have consequence in the circumstance that the non-tested parent is also a carrier for the condition or disorder. In this case, there is a 25 percent chance that a future child would inherit the condition or disorder.

FDA believes that the special controls requiring certain warnings in the device labeling are sufficient to mitigate such risk without further premarket review. The special controls include requiring a

warning statement accurately disclosing the genetic coverage of the test in lay terms, including, as applicable, information on variants not queried by the test, and the proportion of incident disease that is not related to the gene(s) tested. For example, where applicable, the statement would have to include a warning that the test does not or may not detect all genetic variants related to the genetic disease, and that the absence of a variant tested does not rule out the presence of other genetic variants that may be disease related. Or, where applicable, the statement would have to include a warning that the basis for the disease for which the genetic carrier status is being tested is unknown or believed to be non-heritable in a substantial number of people who have the disease, and that a negative test result cannot rule out the possibility that any offspring may be affected with the disease. The statement would have to include any other warnings needed to accurately convey to consumers the degree to which the test is informative for carrier status. The labeling special controls as a whole help ensure that those individuals for whom the test is conducted have the information available to enable them to understand the limitations of the test results prior to the test being performed and after receiving test results and provide context for the use and further interpretation of any results.

B. Well Established Safe and Effective Performance

FDA has generally considered whether the characteristics of the device necessary for its safe and effective performance are well established. Given that autosomal recessive carrier screening gene mutation detection systems were initially classified on February 19, 2015, under the de novo process, a process by which FDA evaluates novel devices anew, FDA has considered other related factors, including whether the performance characteristics that are necessary for the safe and effective use of the device are addressed by the special controls, in combination with general controls.

Clinical validity is addressed through the special controls without the need for premarket notification. Generally, FDA accepts evidence of clinical validity of each variant queried and reported by a test as supported by peer-reviewed journal articles, authoritative summaries of the literature, and/or professional society recommendations during its premarket review. As discussed previously, given the level and nature of scientific evidence necessary to establish autosomal recessive inheritance patterns and corresponding ease of recognizing false or misleading clinical claims for this type of test, clinical validity is assured through the special controls requiring that clinical validity be scientifically well-established in peer-reviewed journal articles, authoritative summaries of the literature, and/or professional society recommendations and that evidence supporting such be publicly posted on the manufacturer's Web site.

Moreover, as discussed previously, applicable special controls help ensure that individuals for whom the tests are conducted are able to understand the testing prior to the test being performed, as well as provide context, including limitations, regarding the clinical validity of the variants reported. These special controls mitigate the risks posed by incorrect test results and the risk that test results are interpreted incorrectly or are misleading.

The special controls for devices of this type require rigorous analytical performance metrics and parameters to be met, which is what FDA would typically assess in its review of analytical performance in a premarket submission. The special control requiring this analytical performance information to be posted on the manufacturer's public Web site will allow FDA, as well as others, to review this information. Together these special controls, described in more detail in this document, obviate the need for premarket notification.

- First, the special controls provide a detailed listing of the protocol requirements and acceptance criteria for all analytical studies (*e.g.,* precision/reproducibility, accuracy, interference, and cross-reactivity).
- Second, the special controls define how, in some cases, analyses must be performed and presented to the person from whom the tests are conducted.
- Third, a very high level of accuracy is prescribed in the special controls.
- Fourth, the special controls also require that devices of this type only use collection devices that are FDA cleared, FDA approved, or classified as 510(k) exempt, with an indication for in vitro diagnostic use in DNA testing. The use of a lawfully marketed collection device intended for such use provides assurances regarding the safety and effectiveness of that component of the device, which in turn helps to assure the safety and effectiveness of the device as a whole.
- Fifth, the special controls limit the distribution of devices of this type, excluding the collection device, to the manufacturer, manufacturer's subsidiaries, and laboratories subject to regulation under the Clinical Laboratory Improvement Amendments. This limitation mitigates risk through lowering the probability of inaccurate test results by ensuring that testing is performed by qualified individuals and in a manner that provides greater assurance of quality of the testing process.
- Sixth, specific statements regarding the probability of test failure and a description of scenarios in which a test can fail are prescribed in the special controls.
- Lastly, the special controls require warnings in the labeling to help ensure that persons for whom the tests are conducted and users are able to understand the testing prior to the test being performed, as well as provide context, including limitations, regarding the analytical validity of the variants reported.

Taken together, these special controls mitigate the risks through lowering the probability of inaccurate test results and increasing the likelihood of user understanding regarding test limitations and performance. FDA believes that given the unique characteristics of an autosomal recessive carrier screening gene mutation detection system, including that both a mother and father must be carriers in order to have a 25 percent chance that their child would have the disorder, these special controls reasonably assure that a legally marketed device of this type will have the characteristics necessary for its safe and effective performance without the need for premarket notification.

C. Anticipated Changes in the Device That Could Affect Safety and Effectiveness Are Readily Detectable by Users or Would Not Materially Increase Risk

The special controls, in combination with the general controls, assure that anticipated changes in the device that could affect safety and effectiveness will either be readily detectable by users or not materially increase risk.

As discussed previously, the special controls include a detailed outline of clinical and analytical performance information that must be generated or obtained and posted on the manufacturer's Web site. Such special controls provide details on how analytical testing must be performed and provide certain performance criteria that the analytical testing must demonstrate have been met. Any changes to the device that could significantly affect safety or effectiveness would require new data or information in support of such changes, which would also have to be posted on

the manufacturer's Web site. The types of permissible changes are limited by the limitations of exemption at § 866.9 (21 CFR 866.9), as discussed in this document.

D. Changes to the Device Would Not Result in a Change in Classification

Subject to the applicable requirements under the special controls, in combination with general controls, changes to a device of this type would not be likely to result in a change in the device's classification. FDA also considered, in proposing to exempt these devices, that these devices would be subject to the limitations described in section IV.

IV. Limitations of Exemption

FDA's proposal to grant an exemption from the premarket notification for an autosomal recessive carrier screening gene mutation detection system applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. FDA proposes that a manufacturer of an autosomal recessive carrier screening gene mutation detection system would still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in § 866.9, except § 866.9(c)(2) to the extent it may include an autosomal recessive carrier screening gene mutation detection system.

FDA added the limitation of exemption from section 510(k) of the FD&C Act for in vitro devices intended for use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism (codified at § 866.9(c)(2)) by notice in the **Federal Register** of January 21, 1998 (63 FR 3142), when FDA exempted 62 types of class II devices from section 510(k) under section 510(m)(1). When FDA later made this limitation of exemption applicable to certain class I devices in 2000, FDA explained that FDA intended that devices used in connection with either familial or acquired genetic disorders be subject to premarket notification requirements because misdiagnosis of either of these disorders would be associated with high morbidity or mortality (65 FR 2296 at 2299). This category of in vitro diagnostic devices is much broader than autosomal recessive carrier screening gene mutation detection, if such a use is included in this category at all. To the extent such a use is included in § 866.9(c)(2), FDA is proposing that this limitation not apply to the exemption of autosomal recessive carrier screening gene mutation detection systems from section 510(k) of the FD&C Act for the reasons that follow.

First, autosomal recessive carrier screening gene mutation detection present very different risks from other tests covered by § 866.9(c)(2), such as tests for screening or diagnosis of genetic disorders in the individuals being tested, as opposed to their offspring. As discussed in detail previously, because carrier screening is only intended to detect heterozygotes (carriers), false positive results would suggest that a person was a carrier of a mutation, but would not contain information that could lead to conclusions of disease for the tested person. Further, no conclusion about an individual's future children could be made given that the carrier status of the child's second parent would need to be known to reach such a conclusion, and even where both parents are truly positive the only conclusion that may be drawn is that the child has a 25 percent likelihood of manifesting the disease. The probability of a both parents receiving false positive carrier results from using a device of this type is vastly smaller than for a single false positive result.

Second, based on FDA's increased understanding of genetic testing and the risks posed by devices of this type, FDA was able to develop special controls to mitigate the risks of false positive and false negative results, as detailed in section III. For example, the special controls requiring demonstration of both analytical and clinical validity, posting of this information on the manufacturer's Web site, consumer comprehension studies, information regarding genetic counseling, and warnings regarding the meaning, context, and limitations of results all reduce the likelihood of false results and of the harms that such may cause. As a result, the risk of false results, as mitigated by the special controls, in combination with general controls, for such device would not be associated with high morbidity or mortality, and FDA is proposing that the limitation of exemption in § 866.9(c)(2) not apply to devices of this type to the extent the limitation includes autosomal recessive carrier screening gene mutation detection.

FDA proposes that an autosomal recessive carrier screening gene mutation detection system is not exempt from the premarket notification requirement if such device: (1) Has an intended use that is different from the intended use of a legally marketed device in that generic type; *e.g.,* the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type; *e.g.,* a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a DNA probe or nucleic acid hybridization or amplification technology rather than culture or immunoassay technology; or (3) is an in vitro device that is intended: for use in the diagnosis, monitoring or screening of neoplastic diseases with the exception of immunohistochemical devices; for measuring an analyte which serves as a surrogate marker for screening, diagnosis, or monitoring of life threatening diseases, such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction, or to monitor therapy; for assessing the risk of cardiovascular diseases; for use in diabetes management; for identifying or inferring the identity of a microorganism directly from clinical material; for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; for noninvasive testing; or for near-patient testing (point of care).

When a device falls within or ''trips'' any of these limitations, 510(k) clearance is required prior to marketing. Following a determination by FDA, through the premarket notification process, that such a device is substantially equivalent to a legally marketed device in the 510(k)-exempt generic type under 21 CFR 866.5940, and compliance with the special controls, future devices with the same indications and technological characteristics would be exempt from premarket notification. If you have questions regarding whether your device's indication for use constitutes a different intended use requiring 510(k) submission, you may contact the Division of Chemistry and Toxicology Devices in the Office of In Vitro Diagnostics and Radiological Health to request a review of your indication for use and any relevant literature.

Based on FDA's review of current scientific literature, FDA would not consider the determination of carrier status by detection of clinically relevant gene mutations associated with the diseases and conditions listed in Table 1 to constitute a different intended use from that of a legally marketed device in the generic type 21 CFR 866.5940 for purposes of § 866.9(a). Thus such uses would be 510(k)-exempt once there is compliance with special controls. A gene mutation detection system indicated for the determination of carrier status by detection of clinically relevant gene mutations associated with Cystic Fibrosis is not 510(k)-exempt since it is a class II device subject to premarket notification and special controls under 21 CFR 866.5900—*Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.*

TABLE 1

Beta Thalassemia
Bloom Syndrome
Canavan Disease
Congenital Disorder of Glycosylation Type 1a (PMM2–CDG)
Autosomal Recessive Connexin 26-Nonsyndromic Hearing Loss
D-Bifunctional Protein Deficiency
Dihydrolipoamide Dehydrogenase Deficiency
Familial Dysautonomia
Familial Mediterranean Fever
Fanconi Anemia Group C
Gaucher Disease
Glycogen Storage Disease Type 1 (1a and 1b)
Gracile Syndrome
Hereditary Fructose Intolerance
Junctional Epidermolysis Bullosa (LAMB3-related)
Leigh Syndrome, French Canadian Type (LSFC)
Autosomal Recessive Limb-girdle Muscular Dystrophy
Maple Syrup Urine Disease
Medium-Chain Acyl-CoA Dehydrogenase (MCAD) Deficiency
Mucolipidosis IV
Autosomal Recessive Neuronal Ceroid Lipofuscinosis (CLN5-related)
Autosomal Recessive Neuronal Ceroid Lipofuscinosis (PPT1-related)
Niemann-Pick Disease—Type A
Nijmegen Breakage Syndrome
Pendred Syndrome
Phenylketonuria
Autosomal Recessive Polycystic Kidney Disease
Primary Hyperoxaluria Type 2 (PH2)
Rhizomelic Chondrodysplasia Punctata Type 1 (RCDP1)
Salla Disease
Sickle Cell Anemia
Sjögren-Larsson Syndrome
Autosomal Recessive Spastic Ataxia of Charlevoix-Saguenay (ARSACS)
Spinal Muscular Atrophy
Tay Sachs Disease
Tyrosinemia Type I
Usher Syndrome Type 1F
Usher Syndrome Type III
Zellweger Syndrome Spectrum

Exemption from the requirement of premarket notification does not exempt a device from other applicable regulatory controls under the FD&C Act, including the applicable general and special controls. Indeed, FDA's decision to propose 510(k) exemption for these devices is based, in part, on the special controls, in combination with general controls, providing sufficiently rigorous mitigations for the risks identified for this generic type.

Subject to the limitations described previously, FDA has determined that the requirement of premarket notification is not necessary to assure the safety and effectiveness of an autosomal recessive carrier screening gene mutation detection system. Accordingly, FDA is announcing its intent to exempt from the premarket notification requirements autosomal recessive carrier screening gene mutation detection systems, subject to the limitations described previously. FDA is publishing this notice in order to obtain comments regarding the proposed exemption.

V. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart, E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

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

Dated: October 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27198 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3815]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with electronic submission of medical device registration and listing.

DATES: Submit either electronic or written comments on the collection of information by December 28, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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