The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, amended, among other sections, section 513(f) of the Federal Food, Drug, and Cosmetic Act. The guidance entitled *New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff*, issued on February 19, 1998, and the draft guidance entitled *Draft Guidance for Industry and Food and Drug Administration Staff – De Novo Classification Process (Evaluation of Automatic Class III Designation)*, issued on October 3, 2011, were developed and issued prior to the enactment of FDASIA, and certain sections of these guidances may no longer be current as a result of FDASIA. The Center for Devices and Radiological Health is currently working on a new draft *de novo* guidance, that when finalized, will represent the FDA's current thinking on this topic. Until the new draft *de novo* guidance is published, please contact 510(k) Staff at 301-796-5640 for information regarding the *de novo* process.

New Section 513(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff

This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Office of Device Evaluation

Document issued on: February 19, 1998

Until May 26, 1998, comments and suggestions regarding this document should be submitted to Docket No. 98D-0082, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 12420 Parklawn Drive (HFA-305), Room 1-23, Rockville, MD 20857. Such comments will be considered when determining whether to amend the current guidance.

After May 26, 1998, comments and suggestions may be submitted at any time for Agency consideration to James Dillard, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact James Dillard at 301-594-1184.

Additional Copies:World Wide Web/CDRH home page http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 199 when prompted for the document shelf number.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

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New Section 513(f)(2) - Evaluation of Automatic Class III Designation,
Guidance for Industry and CDRH Staff
Section 207 (FDAMA); Section 513 (f)(2) of the FDCA; 21 USC 360c(f)(2)

Purpose

The purpose of this memorandum is to provide guidance to Center for Devices and Radiological Health (CDRH) personnel and to manufacturers on the process and procedures to be followed by Office of Device Evaluation (ODE) review staff in implementing new Section 513 (f) (2) of the Federal Food, Drug, and Cosmetic Act (the Act)[1]. This provision, which is referred to as the Evaluation of Automatic Class III Designation provision (also known as "de novo" or "risk-based" classification), was added by Section 207 of the FDA Modernization Act of 1997 (FDAMA). It is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable predicate device.

Background

On November 21, 1997, The Food and Drug Administration Modernization Act of 1997 amended Section 513(f) (21 U.S.C. 360c(f)) to provide a new mechanism to reclassify statutorily classified class III products.

The legislative history of this provision contemplates a process that permits the Secretary (FDA, by delegation) to reclassify certain low risk devices into class I or II on the basis of established risk-based classification criteria when a new device is classified into class III under the statute because there is no predicate device to which it can be found substantially equivalent. Congress included this section to limit unnecessary expenditure of CDRH and manufacturer resources that could occur if low risk devices were subject to premarket approval (PMA) under section 515. The section was not intended to significantly increase the number of not substantially equivalent determinations or to otherwise alter the 510(k) provisions of the Act or CDRH's approach to the 510(k) classification process. Under the new provision, within thirty (30) days after receiving a not substantially equivalent determination (which is a classification order reflecting placement of the device into class III by operation of the statute), the person receiving the classification order may request that a risk-based classification determination be made for the device. The request must provide a description of the device and detailed information and reasons for any recommended classification. FDA will then classify the device based on section 513(a)(1) of the Act, which sets forth the criteria used to classify and reclassify devices.

Not later than sixty (60) days after the date of the submission of such a request, FDA must make a classification determination by written order, placing the device into one of the three statutory device classes. A device placed into class I or II in this written order can then be commercially

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distributed, subject to other applicable provisions of the Act. A device classified into class III may not be marketed based on the classification order and will require an approved premarket application or completed product development protocol (PDP) under section 515 before commercial distribution can commence. Any clinical studies performed with a class III device must be performed in accordance with the investigational device exemption (IDE) provision of the Act (section 520(g)) and implementing regulations (21 CFR 812). A device classified into class I or II under this new provision becomes a predicate device for future premarket notification submissions, which means that any manufacturer may show that a new device is substantially equivalent to this predicate.

Class I is to include devices where general controls by themselves are sufficient to provide reasonable assurance of its safety and effectiveness. Class II is applicable if there is sufficient information to establish special controls which, together with general controls, provide reasonable assurance of safety and effectiveness. Within 30 days after the issuance of an order classifying a device into class I or II under this section, FDA will publish a notice in the Federal Register announcing the classification and the controls necessary to provide reasonable assurance of safety and effectiveness.

This guidance is intended for reference by CDRH staff and manufacturers to outline the process and timelines for reviewing submissions under this Evaluation of Automatic Class III Designation section. Manufacturers are encouraged to contact the Premarket Notification Section, Program Operations Staff, ODE, CDRH at (301) 594-1190 if additional or specific guidance on a particular device is necessary.

The Evaluation of Automatic Class III Designation Process

Under new 513(f)(2), devices that have been found not substantially equivalent due to lack of a predicate may be placed in class I if the general controls described in the Act are sufficient to provide reasonable assurance of safety and effectiveness. If general controls are not adequate, a device will be placed in class II if there is sufficient information to establish special controls which, together with the general controls, provide such assurance. Special controls may include performance standards, postmarket surveillance, patient registries, and development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)). Devices placed into class II are subject to these controls. The Agency will need to reach a conclusion that the reasonable assurance of safety and effectiveness standard is met by the information in the 510(k) and the accompanying request for Evaluation of Automatic Class III Designation as a basis for placing the product in either class I or II. A product will be classified as class III if general controls are not adequate to provide reasonable assurance of safety and effectiveness and there is not sufficient information to establish special controls that would provide such assurance. Attachment 1 outlines the process FDA intends to follow for Evaluation of Automatic Class III Designations under 513(f)(2). While the process is new, its implementation is based on using the types of information and data ordinarily submitted in 510(k)s and/or reclassification petitions.

A. When Evaluation of Automatic Class III Designation May Be Used

The statute limits consideration to those devices that have not been previously classified under the Act, and that have been classified into class III by written notice. The legislative history instructs the Agency to limit consideration to lower risk devices that have been found not substantially equivalent because no predicate device exists. If, during review of a 510(k) submission for such a device, the Agency identifies other issues needing resolution before the Agency can completely review a request for Evaluation of Automatic Class III Designation, those issues should be addressed in the 510(k) review.

A request for classification under 513(f)(2) may be considered only if it is submitted within 30 days following the manufacturer's receipt of an NSE determination. If a manufacturer has not previously submitted a premarket notification (510(k)) or if the NSE order was not received within the previous thirty (30) days, the manufacturer should submit a new 510(k) for the device. Submitting a new 510(k) may also be appropriate if the NSE determination indicates that additional information is likely to be required to establish that general or special controls will permit classification of the device into class I or II under the 513(f)(2) classification process.

Because this new provision of the Act becomes effective February 20, 1998, any manufacturer that has received an NSE determination on or after January 21, 1998, may consider filing a request under 513(f)(2). As an alternative to using the 513(f)(2) classification procedure, a manufacturer may choose to file a reclassification petition in accordance with 21 CFR 860.134. This petition process requires neither prior submission of a 510(k), nor subsequent receipt of an NSE determination. Nor is it limited to requests submitted within 30 days following receipt of such an NSE determination.

B. The Request For Evaluation of Automatic Class III Designation

Under the new section 513(f)(2), submitters of a request for Evaluation of Automatic Class III Designation must describe the device and provide detailed information and, if they elect to recommend a classification, reasons for the classification they recommend. In order to facilitate the classification process, submitters are requested to provide the types of information ordinarily contained in 510(k)s and/or reclassification petitions (please refer to Attachment 2, which describes the Agency's preference on the contents of a request for Evaluation of Automatic Class III Designation).

Submitters are requested to identify the risks and benefits of the device, the general and special controls they believe applicable to the device, and the submitter's recommendation for placement into class I or class II. For devices recommended to be placed in class I, submitters are specifically requested to recommend whether they believe a device should be exempt from the 510(k) requirements and the design controls provisions of the Quality Systems Regulation (QSR). If the submitter believes general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, the submitter is requested to identify the

special controls necessary to provide such assurance, which would provide the Agency with a basis to place the device in class II. Information to support such recommendations should be included in the request. This information will be combined with the previously submitted information contained in the 510(k) premarket notification and considered in FDA's review of the request for Evaluation of Automatic Class III Designation.

Any available data from human experience with the device also should be provided. Human clinical experience will be especially useful to the Agency in determining if and which general and special controls will be necessary to provide reasonable assurance of safety and effectiveness. However, where human clinical data are not available, the submitter may offer arguments based on bench and animal testing results as well as deductive reasoning as to why FDA should classify the product into class I or class II.

If a device is classified into class I or II in response to a request under 513(f)(2), the device may be legally marketed, subject to the Act's other requirements, and becomes a predicate device for subsequent 510(k) submissions.

Procedures for Review by CDRH

In order to be placed in class I or II under the Evaluation of Automatic Class III Designation provision, a device must first have been reviewed in connection with a 510(k) premarket notification. It is important that this review consider all aspects of the device. If the division identifies questions of safety and effectiveness that suggest additional information is needed, these issues should either be addressed through deficiency letters and responses, or the NSE letter should indicate that these issues have not been resolved. This will afford applicants the opportunity to submit a revised 510(k) addressing these concerns before making a request under 513(f)(2). If a device is found not substantially equivalent because a predicate device cannot be identified and the device appears to be a low risk device, the NSE letter to the applicant should indicate that the product may be appropriate for Evaluation of Automatic Class III Designation under 513(f)(2). If it is apparent to FDA staff that appropriate classification under 513(f)(2) may require input from an advisory panel during the sixty (60) day time frame allotted for review of a request, staff should begin arrangements for convening such a panel as early as possible. If, while reviewing the 510(k), the division determines that the device is not a likely candidate for Evaluation of Automatic Class III Designation, the NSE letter should indicate that FDA believes premarket approval will be necessary prior to marketing the device.

Upon receiving a request under 513(f)(2), the FDA will conduct an initial administrative review to confirm that the request contains the necessary information (see Attachment 2). If FDA finds that the request does not have sufficient information for review, the Agency intends to notify the applicant by telephone that the request is incomplete and identify the information needed to permit a substantive review. If the additional information necessary to review the request is not received within thirty (30) days, FDA will maintain the device in class III. Substantive review of a request and final classification will be processed within sixty (60) days of receipt of complete and timely requests by the Document Mail Center. Final action will be by written order classifying the device

into either class I, II, or III. Requests for Evaluation of Automatic Class III Designation should be submitted to:

Document Mail Center, ODE, (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Once a request for Evaluation of Automatic Class III Designation has been submitted, reviewers should apply the criteria set forth in section 513 of the Act. If general and/or special controls are insufficient to provide a reasonable assurance of safety and effectiveness, the device will remain in class III and require premarket approval under section 515 prior to marketing. If special controls are identified which provide the basis for placement into class II, they must be specified and must identify the underlying issue(s) of safety or effectiveness addressed so that they can be applied to other products of a similar type.

The review should be based on the information submitted in the request for Evaluation of Automatic Class III Designation as well as information submitted in the 510(k). The division reviewing the request will be responsible for drafting the written order determining the classification of the device as well as a draft federal register notice announcing the classification of a device into class I or class II. These orders should be in the form of a classification action and identify the applicability of design controls and 510(k) notification for class I products and identify the special controls for class II products. Both the order and the notice should be signed by the Director, Office of Device Evaluation (ODE).

Within thirty (30) days of receipt of the request by the Document Mail Center (DMC), the division reviewing the request should coordinate an issues resolution meeting with the Office Director. Following the issues resolution meeting, the reviewing division should draft the written order as well as the draft federal register notice announcing the classification, using the boilerplates developed for Evaluation of Automatic Class III Designation. These drafts should be completed by day forty-five (45) following receipt of the request. A signed order classifying the device should be sent to the requester by day sixty (60) following receipt of the request. The written order classifying the device shall be the initial classification of the device and any device classified into class I or class II in response to the request for classification under 513(f)(2) will serve as a predicate device for future determinations of substantial equivalence. The Program Operations Staff in ODE will track the Federal register notice announcing class I or class II classifications and ensure the notice will be published within thirty (30) days after the written classification order has been signed.

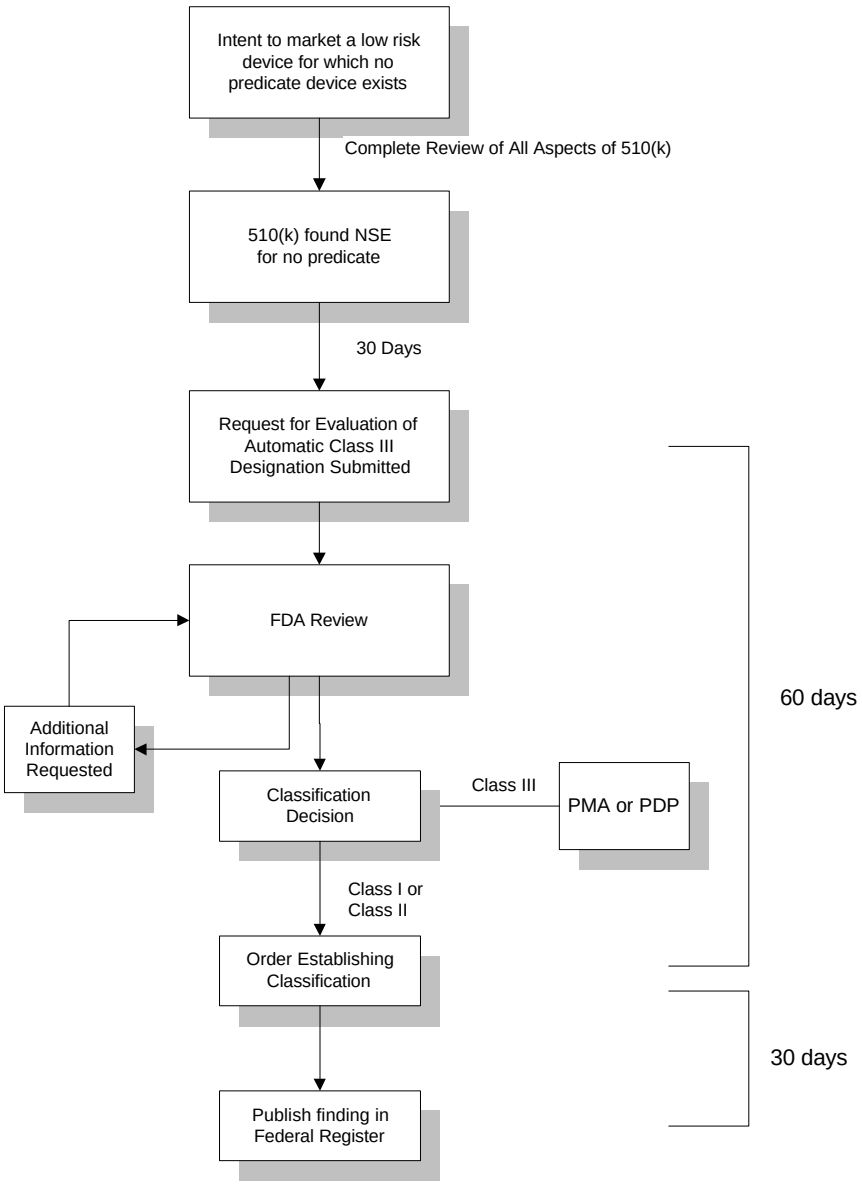
Conclusion

The Center for Devices and Radiological Health believes that the Evaluation of Automatic Class III Designation process can be useful for certain low risk devices that have no predicate. Public input prior to implementation of this guidance was not practicable because the provision allowing

classification under 513(f)(2) becomes effective February 20, 1998. However, comments are welcome and should be addressed to Jim Dillard, Deputy Director DGRD, Center for Devices and Radiological Health, Office of Device Evaluation, 9200 Corporate Boulevard, Rockville, Maryland 20850. The Agency will review all comments and make changes, as appropriate. Interested parties should recognize that procedures and processes may change as the Agency and industry develop experience using this new provision. Changes will be publicized and implemented in accordance with FDA's good guidance practices.

Attachment 1

Evaluation of Automatic Class III Designation Process



Attachment 2

Request for Evaluation of Automatic Class III Designation

In order to facilitate review, the request for Evaluation of Automatic Class III Designation should include the following information:

- A coversheet clearly identifying the submission as "Request for Evaluation of Automatic Class III Designation" under 513(f)(2).
- The 510(k) number under which the device was found not substantially equivalent.
- A statement of cross reference to the information contained in the 510(k).
- The classification being recommended under section 513 of the act.
- A discussion of the potential benefits of the device when compared to the potential or anticipated risks when the device is used as intended.
- A complete discussion of the proposed general and/or special controls to ensure reasonable assurance of the safety and effectiveness of the device, including whether the product should be exempt from premarket review under section 510(k), whether design controls should be applicable, and what special controls would allow the Agency to conclude the device was reasonably likely to be safe and effective for its intended use.
- Any clinical or preclinical data not included in the 510(k) that are relevant to the request.