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FDA/CDRH Webinar

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Medical Device Classification and Reclassification Procedures – Proposed Rule

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Background

- The proposed rule covers classification and reclassification procedures for medical devices
- Classification and reclassification are basic components of FDA's risk-based regulation of devices
- Recently, FDA has been engaged in an effort to finalize the classification of all "pre-amendment" class III for which there has been no "call for PMAs"

Background

Why is FDA Issuing this Proposed Rule:

- To conform Part 860 to FDASIA changes to sections 513(e) and 515(b)
- Increased attention to classification actions because of pre-amendment class III devices
- Part 860 is overdue for an update – last updated in 1998

To Implement Section 608 FDASIA

FDA is proposing changes to its reclassification regulation to conform to new, streamlined procedures required by FDASIA

- FDASIA changed the process for certain classification actions from notice and comment rule-making to a proposed and final order process.
- These changes streamline the procedure by eliminating the requirement for a formal economic impact analysis and taking classification actions outside of EO 12866, establishing Administration review for regulations and certain other actions.

To Implement Section 608 FDASIA (continued)

FDA is proposing changes to its reclassification regulation to conform to new, streamlined procedures required by FDASIA

Section 608 primarily affected the following processes:

- Section 513(e): FDA can reclassify a device when there is new information about the device, or about the kinds of regulatory control that can provide a reasonable assurance of safety and effectiveness.
- Section 515(b): FDA must "call for" an approval application for a device classified into class III.

To Clarify Criteria for Class III (High-Risk) Devices

FDA is also proposing to clarify the criteria for class III (high-risk) devices

The proposed rule is intended to provide:

- ***greater clarity*** about the threshold criteria for classification into class III, namely, whether a device:
  - Is life-sustaining or life-supporting;
  - Is of substantial importance in preventing impairment of human health; OR
  - presents a potential unreasonable risk of illness or injury.
- ***more specificity*** about when special and general controls are insufficient to control risks from such devices.

*http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM384576.pdf.

Clarifies Criteria for Class III (High-Risk) Devices (continued)

FDA is also proposing to clarify the criteria for class III (high-risk) devices

The proposed rule specifies that the following categories of devices meet the statutory standard for classification into class III:

- Devices that present known risks that cannot be controlled;
- Devices for which the risk-benefit profile is unknown or unfavorable;
- Devices for which a full review of manufacturing information is necessary;
- Devices for which premarket review of any change affecting safety or effectiveness is necessary, and
- Certain combination products.

To Clarify Criteria for Class III (High-Risk) Devices (continued)

FDA is also proposing to clarify the criteria for class III (high-risk) devices

Proposed rule would not affect how FDA reviews 510(k)s because FDA reviews 510(k)s under the substantial equivalence standard.

To Improve the Predictability, Transparency, and Consistency of Classification Actions

A general update to the FDA's medical device classification regulation will increase certainty about how devices will be regulated, benefitting industry, device users and FDA staff.

- Part 860 has not been updated since 1998.
- Since that time, interactions with stakeholders have shown the need for greater clarity in the rule , particularly concerning criteria for classification and reclassification into class III.
  - Citizen Petition FDA 2012 P 0747 challenging our use of certain forms describing criteria for classification into class III
  - Reclassification petitions asking for certain class II devices to be classified into class III or for certain III devices to be reclassified into class II
  - Legal and policy challenges to classification decisions and even anticipated classification decisions.

To Improve the Predictability, Transparency, and Consistency of Classification Actions (continued)

A general update to the FDA's medical device classification regulation will increase certainty about how devices will be regulated, benefitting industry, device users and FDA staff.

- Proposed rule would eliminate Form 3429 (Classification Questionnaire) and Form 3427 (Supplement Data Sheet).
- Add definitions of special controls.
- Update terminology (for example, replacing the term "performance standards" with "special controls" and "old/new devices" with "pre/post-amendment devices."

Economic Impact

The proposed rule imposes no significant new burdens and is expected to have modest economic benefits. It is not economically significant.

- Proposed rule is expected to make reclassification process clearer by reducing costs associated with preparing and reviewing reclassification petitions.
- The economic analysis estimates modest estimated annual benefits.

Impact on Panel Meetings

- Implements FDASIA requirement for panels to consider reclassifications and calls for PMAs.
- Clarifies that FDA may consult with panel by telephone, but only for *certain* actions:
  - Initial classification of pre-amendment devices (unclassified)
  - Discretionary panels for post-amendment devices
  - To consider certain reclassification petitions.
- Phone panel procedures do not apply to panels required under 513(e) or 515(b).

Feedback on Proposed Classification/ Reclassification Rule

- FDA considers and addresses in the preamble every comment submitted on a proposed rule.
- FDA encourages submission of electronic or written comments through the normal “notice and comment” process.
- Specifics for submitting comments during the 90-day period can be found in the proposed rule.

Thank you for participating!

Please send your questions to:

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For more information on the regulation of medical devices, visit *CDRH Learn* and *Device Advice* in the Medical Device section of FDA.gov