Overview of Medical Device Classification and Reclassification

U.S. Food & Drug Administration

On July 9, 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA). Section 608(c) of FDASIA requires the FDA to annually post the number and type of medical devices reclassified in the previous calendar year.

This Web page provides an overview of the medical device classification and reclassification processes and includes links to tables that give details about the medical devices reclassified by the FDA each year.

Classification of Medical Devices

The FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.

For more information about the medical device classification process, see Classify Your Medical Device [1].

Reclassification of Medical Devices

Preamendments Devices

A preamendments device is one that was in commercial distribution before May 28, 1976, the date the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) were signed into law. These devices were initially classified as Class I, II, or III.

The FDA may on its own initiative or in response to a petition, reclassify a previously classified preamendments device based on “new information.” This reclassification process is described in section 513(e) of the FD&C Act [2]. For information on the reclassification process under section 513(e) of the FD&C Act, including the number and type of devices reclassified as part of this process since January 1, 2013, see the Reclassification [3] Web page.

Some preamendments device types were initially regulated as Class III through the 510(k) program, with the intent that the FDA would either reclassify them into Class I or II or would keep the Class III classification and call for premarket approval (PMA) applications. In 2009, the FDA kicked off the 515 Program Initiative [4] to finalize the classification of Class III preamendments device types that still required final FDA action. For more information on the status of this program, including the number and type of devices reclassified as part of this process, see the 515 Project Status [5] Web page.

Postamendments Devices

Devices that were not available on the market before the passage of the Medical Device Amendments of 1976 are generally referred to as postamendments devices. These are automatically classified into Class III, regardless of the risk they pose.

Novel postamendments devices of low to moderate risk may be eligible for classification in Class I or II through the *de novo* classification process which is described in section 513(f)(2) of the FD&C Act [2]. For more information on the *de novo* classification process, see Evaluation of Automatic Class III Designation (*De Novo*) Summaries [6].

In addition, a postamendments device may be reclassified according to the process described in 513(f)(3) of the FD&C Act [2].

For more information on the reclassification processes under sections 513(e) and 513(f)(3) of the FD&C Act, including the number and type of devices reclassified as part of these processes, see the Reclassification [3] Web page.

Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm2005371.htm
[2] http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec360c.pdf
[3] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378724.htm
[4] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240310.htm
[5] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm240318.htm
[6] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm