Draft Guidance for Industry and Food and Drug Administration Staff - Medical Device Classification Product Codes

U.S. Food & Drug Administration

You should submit comments and suggestions regarding this draft document within 120 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov [1]. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact (CDRH) Diane Garcia at 301-796-6559 or diane.garcia@fda.hhs.gov [2], or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 301-827-1800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

- Program Operations Staff/Office of Device Evaluation - 301-796-5640
- Product Classification Database [3]
- Office of Regulatory Affairs (ORA) Product Code Builder [4]
- Device Advice – Device Regulation and Guidance [5]
- Device Classification [6]
- Medical Device Listing [7]
- Convenience Kits Guidance [8]
- Medical Device Reporting (MDR) [9]
- Industry Procedures for Section 513(g) Requests for Information [10]
- Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff (De Novo) [11]

[1] An unclassified device is a pre-amendments device for which a classification regulation has not been promulgated. Unclassified devices require submission of a 510(k) premarket notification to CDRH. A not-classified device is a post-amendments device that the Agency has not yet reviewed or for which the Agency has not made a final decision. A pre-amendments device is a device that was on the market prior to the enactment of the Medical Device Amendments to the FD&C Act on May 28, 1976.

[2] See Guidance for Evaluation of Automatic Class III Designation [11].

[3] See Convenience Kits Interim Regulatory Guidance [8].

[4] For additional information regarding HUD designation, refer to information on the FDA website [12].

[5] Product Classification Database [3]

[6] Product Code Builder (For Foods) [13]

[7] See 21 CFR Part 807.

[8] Device Advice: Comprehensive Regulatory Assistance [5]

[9] How to Register and List [14]

[10] Product Classification Database [3]

[11] See 21 CFR Part 807.

[12] Refer to the Draft Guidance for Industry and FDA Staff: FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act [10] on FDA's website, and the Draft Guidance for Industry and FDA Staff: User Fees for 513(g) Requests for Classification Information [15].

[13] See https://www.cms.gov/ [16]

SOURCE [17]

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Links:
[1] http://www.regulations.gov
[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/mailto:diane.garcia@fda.hhs.gov
[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
[4] http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm

[5] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm
[7] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080216.htm
[9] http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
[10] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm
[11] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm
[12] http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/DesignatingHumanitarianUseDevicesHUDS/default.htm
[13] http://www.fda.gov/ForIndustry/ImportProgram/ProductCodeBuilderforFoods/default.htm
[14] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm
[15] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm
[16] https://www.cms.gov/
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