Subpart F—Therapeutic Devices

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

SOURCE: 53 FR 23872, June 24, 1988, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 878 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a general and plastic surgery device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.*.

[53 FR 23872, June 24, 1988, as amended at 67 FR 77676, Dec. 19, 2002; 78 FR 18233, Mar. 26, 2013]

§ 878.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the