

Subpart F—Therapeutic Devices

- 876.5010 Biliary catheter and accessories.
- 876.5020 External penile rigidity devices.
- 876.5030 Continent ileostomy catheter.
- 876.5090 Suprapubic urological catheter and accessories.
- 876.5130 Urological catheter and accessories.
- 876.5160 Urological clamp for males.
- 876.5210 Enema kit.
- 876.5220 Colonic irrigation system.
- 876.5250 Urine collector and accessories.
- 876.5270 Implanted electrical urinary continence device.
- 876.5280 Implanted mechanical/hydraulic urinary continence device.
- 876.5310 Nonimplanted, peripheral electrical continence device.
- 876.5320 Nonimplanted electrical continence device.
- 876.5365 Esophageal dilator.
- 876.5450 Rectal dilator.
- 876.5470 Ureteral dilator.
- 876.5520 Urethral dilator.
- 876.5540 Blood access device and accessories.
- 876.5600 Sorbent regenerated dialysate delivery system for hemodialysis.
- 876.5630 Peritoneal dialysis system and accessories.
- 876.5665 Water purification system for hemodialysis.
- 876.5820 Hemodialysis system and accessories.
- 876.5830 Hemodialyzer with disposable insert (Kiil type).
- 876.5860 High permeability hemodialysis system.
- 876.5870 Sorbent hemoperfusion system.
- 876.5880 Isolated kidney perfusion and transport system and accessories.
- 876.5885 Tissue culture media for human ex vivo tissue and cell culture processing applications.
- 876.5895 Ostomy irrigator.
- 876.5900 Ostomy pouch and accessories.
- 876.5920 Protective garment for incontinence.
- 876.5955 Peritoneo-venous shunt.
- 876.5970 Hernia support.
- 876.5980 Gastrointestinal tube and accessories.
- 876.5990 Extracorporeal shock wave lithotripter.

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

SOURCE: 48 FR 53023, Nov. 23, 1983, unless otherwise noted.

Subpart A—General Provisions**§ 876.1 Scope.**

(a) This part sets forth the classification of gastroenterology-urology 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 pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

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

(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/cdrh/guidance.html>.

[52 FR 17737, May 11, 1987; 52 FR 22577, June 12, 1987, as amended at 69 FR 77623, Dec. 28, 2004]

§ 876.3 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 act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the