Subpart B—Diagnostic Devices
876.1075 Gastroenterology-urology biopsy instrument.
876.1300 Ingestible telemetric gastrointestinal capsule imaging system.
876.1400 Stomach pH electrode.
876.1500 Endoscope and accessories.
876.1620 Urodynamics measurement system.
876.1725 Gastrointestinal motility monitoring system.
876.1735 Electrogastrography system.
876.1800 Urine flow or volume measuring system.

Subpart C—Monitoring Devices
876.2040 Enuresis alarm.

Subpart D—Prosthetic Devices
876.3350 Penile inflatable implant.
876.3630 Penile rigidity implant.
876.3750 Testicular prosthesis.

Subpart E—Surgical Devices
876.4020 Fiberoptic light ureteral catheter.
876.4270 Colostomy rod.
876.4300 Endoscopic electrosurgical unit and accessories.
876.4370 Gastroenterology-urology evacuator.
876.4400 Hemorrhoidal ligator.
876.4480 Electrohydraulic lithotriptor.
876.4500 Mechanical lithotriptor.
876.4530 Gastroenterology-urology fiberoptic retractor.
876.4590 Ribdam.
876.4650 Interlocking urethral sound.
876.4620 Ureteral stent.
876.4650 Water jet renal stone dislodger system.
876.4680 Ureteral stone dislodger.
876.4730 Manual gastroenterology-urology surgical instrument and accessories.
876.4770 Urethrotome.
876.4890 Urological table and accessories.

Subpart F—Therapeutic Devices
876.5010 Biliary catheter and accessories.
876.5320 Implantable mechanical/hydraulic urinary continence device.
876.5310 Nonimplanted, peripheral electrical continence device.
876.5280 Implanted mechanical/hydraulic urinary 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.
876.5660 Sorbent regenerated dialysate delivery system for hemodialysis.
876.5630 Peritoneal dialysis system and accessories.
876.5655 Water purification system for hemodialysis.
876.5630 Hemodialysis system and accessories.
876.5630 Hemodialyzer with disposable insert (Kill type).
876.5660 High permeability hemodialysis system.
876.5670 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.

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

Subpart A—General Provisions

Editorial Note: Nomenclature changes to part 876 appear at 73 FR 35341, June 23, 2008.

§ 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 premarket notification submission for a device under part 807 may not show merely that the device is accurately...
§ 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 act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA’s issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a “new” device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17737, May 11, 1987]

§ 876.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of
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premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in §812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2316, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 876.1075 Gastroenterology-urology biopsy instrument.

(a) Identification. A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

(b) Classification. (1) Class II (performance standards).

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §876.9.


§ 876.1300 Ingestible telemetric gastrointestinal capsule imaging system.

(a) Identification. An ingestible telemetric gastrointestinal capsule imaging system is used for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an antenna array, a receiving/recording unit, a data storage device, computer software to process the images, and accessories.

(b) Classification. Class II (special controls). The special control is FDA's guidance, "Class II Special Controls