

§ 874.5550

before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a tongs antichoke device that was in commercial distribution before May 28, 1976. Any other tongs antichoke device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[51 FR 40389, Nov. 6, 1986, as amended at 64 FR 18329, Apr. 14, 1999]

§ 874.5550 Powered nasal irrigator.

(a) *Identification.* A powered nasal irrigator is an AC-powered device intended to wash the nasal cavity by means of a pressure-controlled pulsating stream of water. The device consists of a control unit and pump connected to a spray tube and nozzle.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2316, Jan. 14, 2000]

§ 874.5800 External nasal splint.

(a) *Identification.* An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 59 FR 63009, Dec. 7, 1994]

§ 874.5840 Antistammering device.

(a) *Identification.* An antistammering device is a device that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitant or repetitive speech.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

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PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

Subpart A—General Provisions

Sec.

876.1 Scope.

876.3 Effective dates of requirement for premarket approval.

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

Subpart B—Diagnostic Devices

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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

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Subpart D—Prosthetic Devices

876.3350 Penile inflatable implant.

876.3630 Penile rigidity implant.

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Subpart E—Surgical Devices

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876.4300 Endoscopic electrosurgical unit and accessories.

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876.4400 Hemorrhoidal ligator.

876.4480 Electrohydraulic lithotripter.

876.4500 Mechanical lithotripter.

876.4530 Gastroenterology-urology fiberoptic retractor.

876.4560 Ribdam.

876.4590 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.

876.5030 Continent ileostomy catheter.

876.5090 Suprapubic urological catheter and accessories.

876.5130 Urological catheter and accessories.