

§ 874.5350

support a patient during an otologic examination while providing specialized features for examination and treatment. The unit consists of a patient chair and table, drawers for equipment, suction and blowing apparatus, and receptacles for connection of specialized lights and examining instruments.

(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]

§ 874.5350 Suction antichoke device.

(a) *Identification*. A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of PDP is required*. A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any suction antichoke device that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to a suction antichoke device that was in commercial distribution before May 28, 1976. Any other suction 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; 65 FR 2316, Jan. 14, 2000]

§ 874.5370 Tongs antichoke device.

(a) *Identification*. A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient. This generic type of device includes a plastic instrument with serrated ends that is inserted into the airway in a blind manner to grasp and extract foreign

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objects, and a stainless steel forceps with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of PDP is required*. A PMA or a notice of completion of a PDP for a device is required to be filed with the Food and Drug Administration on or before July 13, 1999 for any tongs antichoke device that was in commercial distribution 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 (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[51 FR 40389, Nov. 9, 1986, as amended at 52 FR 32111, Aug. 25, 1987; 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 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]

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

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 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.

876.5020 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 *in 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 Periteneo-venous shunt.

876.5970 Hernia support.

876.5980 Gastrointestinal tube and accessories.

876.5990 Extracorporeal shock wave lithotripter.

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