

§ 874.4720

mediastinal disease, or to remove foreign bodies from the esophagus. When inserted, the device extends from the area of the hypopharynx to the stomach. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification*. Class II.

§ 874.4720 Mediastinoscope and accessories.

(a) *Identification*. A mediastinoscope and accessories is a tubular tapered electrical endoscopic device with any of a group of accessory devices which attach to the mediastinoscope and is intended to examine or treat tissue in the area separating the lungs. The device is inserted transthoracically and is used in diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification*. Class II.

§ 874.4750 Laryngostroboscope.

(a) *Identification*. A laryngostroboscope is a device that is intended to allow observation of glottic action during phonation. The device operates by focusing a stroboscopic light through a lens for direct or mirror reflected viewing of glottic action. The light and microphone that amplifies acoustic signals from the glottic area may or may not contact the patient.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in

21 CFR Ch. I (4-1-22 Edition)

subpart E of part 807 of this chapter subject to the limitations in § 874.9.

[55 FR 48440, Nov. 20, 1990, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 874.4760 Nasopharyngoscope (flexible or rigid) and accessories.

(a) *Identification*. A nasopharyngoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the nasopharyngoscope and is intended to examine or treat the nasal cavity and nasal pharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel and flexible plastic. This generic type of device includes the antroscope, nasopharyngolaryngoscope, nasosinuscope, nasoscope, postrhinoscope, rhinoscope, salpingoscope, flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification*. Class II.

§ 874.4770 Otoscope.

(a) *Identification*. An otoscope is a device intended to allow inspection of the external ear canal and tympanic membrane under magnification. The device provides illumination of the ear canal for observation by using an AC- or battery-powered light source and an optical magnifying system.

(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 only when used in the external ear canal.

[55 FR 48440, Nov. 20, 1990, as amended at 61 FR 1122, Jan. 16, 1996; 66 FR 38801, July 25, 2001]

§ 874.4780 Intranasal splint.

(a) *Identification*. An intranasal splint is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. The intranasal

Food and Drug Administration, HHS

§ 874.5370

splint is constructed from plastic, silicone, or absorbent material.

(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.

[64 FR 10949, Mar. 8, 1999]

§ 874.4800 Bone particle collector.

(a) *Identification.* A bone particle collector is a filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.

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

[64 FR 10949, Mar. 8, 1999]

Subpart F—Therapeutic Devices

§ 874.5220 Ear, nose, and throat drug administration device.

(a) *Identification.* An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.

(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. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[51 FR 40389, Nov. 6, 1986, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38801, July 25, 2001]

§ 874.5300 Ear, nose, and throat examination and treatment unit.

(a) *Identification.* An ear, nose, and throat examination and treatment unit is an AC-powered device intended to

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