

§ 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