wavelength peaks of 488 and 514 nanometers. In otology, the device is used
for the purpose of coagulating and vaporizing soft and fibrous tissues, in-
cluding osseous tissue. In rhinology and laryngology, the device is used to
coagulate and vaporize soft and fibrous tissues, but not including osseous tis-
sues.

(b) **Classification.** Class II.

[58 FR 29534, May 21, 1993]

§ 874.4500 Ear, nose, and throat microsurgical carbon dioxide laser.

(a) **Identification.** An ear, nose, and throat microsurgical carbon dioxide laser is a device intended for the sur-
gical excision of tissue from the ear, nose, and throat area. The device is
used, for example, in microsurgical procedures to excise lesions to in-
trons of the vocal cords and adjacent areas.

(b) **Classification.** Class II.

§ 874.4680 Bronchoscope (flexible or rigid) and accessories.

(a) **Identification.** A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a

group of accessory devices which attach to the bronchoscope and is in-
tended to examine or treat the larynx and tracheobronchial tree. It is typi-
cally used with a fiberoptic light source and carrier to provide illumina-
tion. The device is made of materials such as stainless steel or flexible plas-
tic. 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.

§ 874.4710 Esophagoscope (flexible or rigid) and accessories.

(a) **Identification.** An esophagoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a
group of accessory devices which attach to the esophagoscope and is in-
tended to examine or treat esophageal
malfunction symptoms, esophageal or mediastinal disease, or to remove for-
eign bodies from the esophagus. When
inserted, the device extends from the area of the hypopharynx to the stom-
ach. 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 in-
tended to examine or treat tissue in the area separating the lungs. The de-
vice 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 illu-
mination. The device is made of mate-
rials such as stainless steel. This ge-
eric type of device includes the flexi-
bile 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 mir-
ror reflected viewing of glottic action. The light and microphone that ampli-
fies acoustic signals from the glottic area may or may not contact the pa-
tient.

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