The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(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.


§ 874.4175 Nasopharyngeal catheter.

(a) Identification. A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.

(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.


§ 874.4250 Ear, nose, and throat electric or pneumatic surgical drill.

(a) Identification. An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur (§874.4140), for the controlled incision or removal of bone in the ear, nose, and throat area.

(b) Classification. Class II.

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(a) Identification. An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass of plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.

(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.


§ 874.4490 Argon laser for otology, rhinology, and laryngology.

(a) Identification. The argon laser device for use in otology, rhinology, and laryngology is an electro-optical device which produces coherent, electromagnetic radiation with principal