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.


§ 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]

$\$ 874.5550$ 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.


$\$ 874.5800$ 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.


$\$ 874.5840$ Antistammering device.

(a) Identification. An antistammering device is a device that electronically generates a noise when activated or