

§ 872.6890

21 CFR Ch. I (4–1–14 Edition)

§ 872.6890 Intraoral dental wax.

(a) *Identification.* Intraoral dental wax is a device made of wax intended to construct patterns from which custom made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is intended to make a pattern of a patient's bite to make study models of the teeth.

(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 §872.9. 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.

[52 FR 30097, Aug. 12, 1987, as amended at 59 FR 63009, Dec. 7, 1994; 66 FR 38800, July 25, 2001]

PART 874—EAR, NOSE, AND THROAT DEVICES

Subpart A—General Provisions

Sec.

874.1 Scope.

874.3 Effective dates of requirement for premarket approval.

874.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

Subpart B—Diagnostic Devices

874.1050 Audiometer.

874.1060 Acoustic chamber for audiometric testing.

874.1070 Short increment sensitivity index (SISI) adapter.

874.1080 Audiometer calibration set.

874.1090 Auditory impedance tester.

874.1100 Earphone cushion for audiometric testing.

874.1120 Electronic noise generator for audiometric testing.

874.1325 Electroglottograph.

874.1500 Gustometer.

874.1600 Olfactory test device.

874.1800 Air or water caloric stimulator.

874.1820 Surgical nerve stimulator/locator.

874.1925 Toynbee diagnostic tube.

Subpart C [Reserved]

Subpart D—Prosthetic Devices

874.3300 Hearing aid.

874.3305 Wireless air-conduction hearing aid.

874.3310 Hearing aid calibrator and analysis system.

874.3320 Group hearing aid or group auditory trainer.

874.3330 Master hearing aid.

874.3375 Battery-powered artificial larynx.

874.3400 Tinnitus masker.

874.3430 Middle ear mold.

874.3450 Partial ossicular replacement prosthesis.

874.3495 Total ossicular replacement prosthesis.

874.3540 Prosthesis modification instrument for ossicular replacement surgery.

874.3620 Ear, nose, and throat synthetic polymer material.

874.3695 Mandibular implant facial prosthesis.

874.3730 Laryngeal prosthesis (Taub design).

874.3760 Sacculotomy tack (Cody tack).

874.3820 Endolymphatic shunt.

874.3850 Endolymphatic shunt tube with valve.

874.3880 Tympanostomy tube.

874.3900 Nasal dilator.

874.3930 Tympanostomy tube with semipermeable membrane.

874.3950 Transcutaneous air conduction hearing aid system.

Subpart E—Surgical Devices

874.4100 Epistaxis balloon.

874.4140 Ear, nose, and throat bur.

874.4175 Nasopharyngeal catheter.

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

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

874.4420 Ear, nose, and throat manual surgical instrument.

874.4490 Argon laser for otology, rhinology, and laryngology.

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

874.4680 Bronchoscope (flexible or rigid) and accessories.

874.4710 Esophagoscope (flexible or rigid) and accessories.

874.4720 Mediastinoscope and accessories.

874.4750 Laryngostroboscope.

874.4760 Nasopharyngoscope (flexible or rigid) and accessories.

874.4770 Otoscope.

874.4780 Intranasal splint.

874.4800 Bone particle collector.

Subpart F—Therapeutic Devices

874.5220 Ear, nose, and throat drug administration device.

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