Food and Drug Administration, HHS

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.

§ 872.6880 Preformed impression tray.

(a) Identification. A preformed impression tray is a metal or plastic device intended to hold impression material, such as alginate, to make an impression of a patient’s teeth or alveolar process (bony tooth sockets) to reproduce the structure of a patient’s teeth and gums.

(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.

§ 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.

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.
874.1350 Gustometer.
874.1360 Olfactory test device.
874.1400 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.
874.3310 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.
874.3455 Total ossicular replacement prosthesis.
874.3540 Prosthesis modification instrument for ossicular replacement surgery.
874.3620 Ear, nose, and throat synthetic polymer material.