§ 872.6870 Disposable fluoride tray.

(a) Identification. A disposable fluoride tray is a device made of styrofoam intended to apply fluoride topically to the teeth. To use the tray, the patient bites down on the tray which has been filled with a fluoride solution.

(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.


§ 872.6880 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.


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 Electroglographograph.
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]