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defects in teeth. This device also includes the individual component devices, mercury and amalgam alloy, when intended to be combined with each other to form dental amalgam.

(b) Classification. Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy.” See §872.1(e) for the availability of this guidance document.

[74 FR 38714, Aug. 4, 2009]

§ 872.3080 Mercury and alloy dispenser.

(a) Identification. A mercury and alloy dispenser is a device with a spring-activated valve intended to measure and dispense into a mixing capsule a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets.

(b) Classification. Class I (general controls). The device is exempt from the premarketing notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.


§ 872.3100 Dental amalgamator.

(a) Identification. A dental amalgamator is a device, usually AC-powered, intended to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The mixed dental amalgam material is intended for filling dental cavities.

(b) Classification. Class I (general controls). The device is exempt from the premarketing notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.


§ 872.3110 Dental amalgam capsule.

(a) Identification. A dental amalgam capsule is a container device in which silver alloy is intended to be mixed with mercury to form dental amalgam.

(b) Classification. Class I (general controls). The device is exempt from the premarketing notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.


§ 872.3130 Preformed anchor.

(a) Identification. A preformed anchor is a device made of austenitic alloys or alloys containing 75 percent or greater gold or metals of the platinum group intended to be incorporated into a dental appliance, such as a denture, to help stabilize the appliance in the patient’s mouth.

(b) Classification. Class I (general controls). The device is exempt from the premarketing notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.


§ 872.3140 Resin applicator.

(a) Identification. A resin applicator is a brushlike device intended for use in spreading dental resin on a tooth during application of tooth shade material.

(b) Classification. Class I (general controls). The device is exempt from the premarketing 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, the device is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exceptions of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.


§ 872.3150 Articulator.

(a) Identification. An articulator is a mechanical device intended to simulate movements of a patient’s upper and lower jaws. Plaster casts of the patient’s teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient’s jaws. An articulator is intended to fit...