the maxilla for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position to generate meaningful output, either directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components.

(b) **Classification.** Class II (special controls). The special control for this device is FDA’s “Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices.” 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 premarket 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 caries.

(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.


§ 872.3110 Dental amalgam capsule.

(a) **Identification.** A dental amalgam capsule is a container device in which