§ 872.2060 Jaw tracking device.

(a) Jaw tracking device for monitoring mandibular jaw positions relative to the maxilla—(1) Identification. A jaw tracking device for monitoring mandibular jaw positions relative to the maxilla is a system used to monitor temporomandibular joint sounds. The device detects and records sounds made by the temporomandibular joint.

(2) Classification. Class I. The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to §872.9.

(b) Jaw tracking device for interpretation of mandibular jaw positions for the diagnosis—(1) Identification. A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla is a nonpowered or electrically powered device that measures and records anatomical distances and angles in three dimensional space, to determine the relative position of the mandible with respect to the location and position of the maxilla, while at rest and during jaw movement.

(2) Classification. Class I (general controls). The device is exempt from the premarket notification provisions of subpart E of part 807 of this chapter subject to §872.9.