

§ 872.1870

subpart E of part 807 of this chapter subject to the limitations in § 872.9.

[52 FR 30097, Aug. 12, 1987, as amended at 61 FR 1121, Jan. 16, 1996; 66 FR 38797, July 25, 2001]

§ 872.1870 Sulfide detection device.

(a) *Identification.* A sulfide detection device is a device consisting of an AC-powered control unit, probe handle, probe tips, cables, and accessories. This device is intended to be used in vivo, to manually measure periodontal pocket probing depths, detect the presence or absence of bleeding on probing, and detect the presence of sulfides in periodontal pockets, as an adjunct in the diagnosis of periodontal diseases in adult patients.

(b) *Classification.* Class II (special controls) prescription use in accordance with § 801.109 of this chapter; conformance with recognized standards of biocompatibility, electrical safety, and sterility; clinical and analytical performance testing, and proper labeling.

[63 FR 59717, Nov. 5, 1998]

§ 872.1905 Dental x-ray film holder.

(a) *Identification.* A dental x-ray film holder is a device intended to position and to hold x-ray film inside the mouth.

(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 also 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.

[52 FR 30097, Aug. 12, 1987, as amended at 54 FR 13830, Apr. 5, 1989; 66 FR 38797, July 25, 2001]

§ 872.2050 Dental sonography device.

(a) *Dental sonography device for monitoring—(1) Identification.* A dental sonography device for monitoring is an electrically powered device, intended to be used to monitor

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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) *Dental sonography device for interpretation and diagnosis—(1) Identification.* A dental sonography device for interpretation and diagnosis is an electrically powered device, intended to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device detects, records, displays, and stores sounds made by the temporomandibular joint during jaw movement. The device interprets these sounds to generate meaningful output, either directly or by connection to a personal computer. The device may be part of a system of devices, contributing joint sound information to be considered with data from other diagnostic components.

(2) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices."

[68 FR 67367, Dec. 2, 2003]

§ 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 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.

(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