§ 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.

§ 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 provisions of subpart E of part 807 of this chapter subject to §872.9.

§ 872.2050 Dental sonography device.

(a) Dental sonography device for monitoring mandibular jaw positions relative to the maxilla—(1) Identification. A dental sonography device for monitoring is an electrically powered device, intended to be 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 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.”