§ 872.2060 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 a 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]

§ 872.3070 Dental amalgam, mercury, and amalgam alloy.

(a) Identification. Dental amalgam is a device that consists of a combination of elemental mercury, supplied as a liquid in bulk, sachet, or predosed capsule form, and amalgam alloy composed primarily of silver, tin, and copper, supplied as a powder in bulk, tablet, or predosed capsule form, for the direct filling of carious lesions or structural