

§ 1260.22 Technical publications and reports.**Technical Publications and Reports
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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 872**

[Docket No. 2002N-0305]

**Medical Devices: Classification of the
Dental Sonography Device and Jaw
Tracking Device**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the dental sonography device into class I, when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA is classifying the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for this device. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of

1997 (FDAMA) and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: This rule is effective January 2, 2004.

FOR FURTHER INFORMATION CONTACT:

Mary S. Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

SUPPLEMENTARY INFORMATION:**I. Background**

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94-295), the SMDA (Public Law 101-629), and FDAMA (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices as a function of the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) issues, under section 513(i) of the act, an order finding the device as substantially equivalent to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to preamendments devices by means of premarket notification

procedures as delineated in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments type device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Consistent with the act and the regulations, FDA consulted with the Dental Products Advisory Panel (the Panel), an FDA advisory committee, regarding the classification of the dental sonography device and the jaw tracking device.

II. Regulatory History of the Device

In the **Federal Register** of August 14, 2002 (67 FR 52901), FDA proposed to classify the dental sonography device into class I when it is used to monitor temporomandibular joint sounds, and into class II, when it is used to interpret temporomandibular joint sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain. FDA also proposed to classify the jaw tracking device into class I, when it is used to monitor mandibular jaw positions relative to the maxilla, and into class II, when it is used to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain.

FDA provided an opportunity for interested persons to comment on the proposed regulation and guidance document until November 12, 2002. FDA received one comment from a consumer, however, the comment was irrelevant to the proposed rule because it was referring to a different device. A manufacturer commented that the identification of the class II sonography could be read to place a device in class II even if it does not interpret sounds. The comment said that a device is appropriately in class II if it interprets sounds. The comment further suggested that FDA should define "interpret" to mean that the device provides a specific diagnosis and not just meaningful output.

FDA agrees that the identification may not have been clear and has revised § 872.2050(b) by combining the last two sentences to clarify that interpretation is a necessary part of the identification. FDA disagrees that "interpret" should mean that a device provides a specific diagnosis. FDA believes that it is necessary that the manufacturer of a class II dental sonography device that