FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. FAA amends § 39.13 by adding a new airworthiness directive (AD) to read as follows:

Moravan A.S.: Docket No. 99–CE–71–AD

(a) *What airplanes are affected by this AD?* This AD affects the following airplane models and serial numbers that are certificated in any category:

Model	Serial Nos.
Z–143L	All serial numbers up to and including 0029, except 0025 and 0027.
Z–242L	All serial numbers up to and including 0733.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to prevent the engine crankcase ventilation lines from freezing during flight in cold weather (winter) conditions, which could result in oil leaking from the engine. Such a condition could lead to engine failure.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
Modify the engine vent lines	Within the next 100 hours time-in-service after the effective date of this AD.	In accordance with Moravan Mandatory Service Bulletin Z 242L/19a—Rev. 3, Z vent service after the 143L/20a, dated April 30, 1999.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Small Airplane Directorate, approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 1: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; facsimile: (816) 329–4090.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *How do I get copies of the documents referenced in this AD?* You may get copies of the documents referenced in this AD from Moravan, Inc., 765 81 Otrokovice, Czech Republic; telephone: +420 67 767 3940; facsimile: +420 67 792 2103. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

Note 2: The subject of this AD is addressed in Czech Republic AD Number CAA–AD–042/1999, August 18, 1999.

Issued in Kansas City, Missouri, on August 7, 2002.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–20516 Filed 8–13–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N–0305]

Dental Devices; Classification of the Dental Sonography Device and the Jaw Tracking Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing 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 is also proposing 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 is publishing the recommendations of the Dental Products Advisory Panel (the panel) regarding the classification of these devices in this document. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control for the class II devices if this proposal becomes final.

DATES: Submit written or electronic comments by November 12, 2002.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

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 Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (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, depending on 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, 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.

A device that was not in commercial distribution before May 28, 1976, generally referred to as a postamendments device, is 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: (1) The device is reclassified into class I or II; (2) FDA 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) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of the premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Hereafter, these are referred to as ''reserved criteria.'' Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA. FDA believes that certain changes to devices within a generic type that is generally exempt may make the device intended for a use which is of substantial importance in preventing impairment of human health or may make the device present a potential unreasonable risk of illness or injury. Accordingly, devices changed in this manner would fall within the reserved criteria under section 510(l) of the act and would require premarket notification. For example, FDA considers a class I device to be subject to premarket notification requirements if the device operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.

FDAMA also added a new section 510(m) to the act. New section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Recommendation of the Panel

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA published a final rule classifying dental devices. At that time, FDA was not aware that the dental sonography device and the jaw tracking device were preamendments devices, and inadvertently omitted classifying them.

Consistent with the act and the regulations, at a public meeting, held on August 4, 1998, FDA consulted with the panel, an FDA advisory committee, regarding the classification of these devices.

A. Identification

FDA is proposing the following device identifications based on the panel's recommendation and the agency's review:

1. The class I dental sonography device is an electrically powered device, intended to be used to monitor temporomandibular joint sounds. The device is used to detect and record sounds made by the temporomandibular joint.

2. The class II dental sonography device 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.

3. The class I jaw tracking device is a nonpowered or electrically powered device used to monitor mandibular jaw positions relative to the maxilla. The device 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.

4. The class II jaw tracking device is an electrically powered device, intended to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. The device measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about joint position. The device interprets jaw position to generate meaningful output, directly or by connection to a personal computer. The device may be a part of a system of devices, contributing jaw position information to be considered with data from other diagnostic components.

B. Recommended Classification of the Panel

During a public meeting, held on August 4, 1998, the panel made the classification recommendations (Ref. 1) for the dental sonography device and the jaw tracking device. The panel recommended that these devices be classified into class I (general controls), and that the devices should be subject to premarket notification. The panel also recommended that these devices be restricted to sale by, or on the order of a licensed dentist or physician (§ 801.109 (21 CFR 801.109)).

C. Summary of Reasons for Recommendation

The panel concluded that safety and effectiveness of the dental sonography device and the jaw tracking device can reasonably be assured by general controls. Specifically, the panel believed that safety and effectiveness of both devices can be reasonably assured by registration and listing (section 510 of the act); general requirements concerning reports (21 CFR 820.180) and complaint files (21 CFR 820.198); and good manufacturing practices requirements (section 520(f) of the act (21 U.S.C. 360j(f).) The panel also recommended that these devices be restricted to sale by, or on the order of a licensed dentist or physician (§ 801.109).

D. Summary of the Data Upon Which the Recommendation Was Based

The panel believes that these devices have provided dental practitioners adjunctive diagnostic information, as a part of the treatment of temporomandibular joint disorders, for over 23 years. When used with other dental devices and clinical techniques, these devices help the clinician to diagnose symptoms related to malfunction of the temporomandibular joint and associated musculature.

After reviewing the literature provided to panel members by FDA (Refs. 2 to 34); information provided by device manufacturers; several panel members' personal knowledge of and clinical experience with the devices; and in consideration of the consensus derived from the open panel discussion, the panel gave the following reasons in support of its recommendation to classify these devices into class I: (1) The devices provide adjunctive information in the form of temporomandibular joint sounds and relative jaw position, not otherwise available to the clinician; (2) no invasive procedures are required; (3) no energy is applied to craniofacial structures; and (4) the devices have been used for many years without documented medical devices reports or other published incident reports.

E. Risks to Health

The panel identified the following risks to health associated with the dental sonography device and the jaw tracking device:

1. Electrical Interference

Electrical interference generated by these devices may affect diagnostic and therapeutic medical devices, such as certain types of cardiac pacemakers. Manufacturers should validate the isolation of electrical circuitry of these devices from other medical devices.

2. Improper Treatment

There is no general consensus or established standard of care regarding interpretation of the output of these devices. Therefore, a misdiagnosis of a condition or abnormality may result in improper or unnecessary therapeutic intervention. The outputs of these devices are adjunctive to other diagnostic and therapeutic modalities.

III. Proposed Classification

FDA concurs that the dental sonography device and the jaw tracking device intended to be used for monitoring sounds made by the temporomandibular joint and mandibular jaw positions relative to the maxilla, respectively, should be classified into class I (general controls). General controls would provide reasonable assurance of safety and effectiveness of these devices for these intended uses. FDA, however, believes that the dental sonography device and jaw tracking device intended to interpret temporomandibular joint sounds and mandibular jaw positions for the diagnosis of temporomandibular joint disorders and associated orofacial pain should be classified into class II (special controls). Premarket notifications for dental sonography and jaw tracking devices with these intended uses should include clinical data to demonstrate performance, as well as labeling instructing the user on proper technique, interpretation of the device outputs, and appropriate warnings and precautions. FDA tentatively concurs with the panel's recommendation that these devices should be restricted to sale by or on the order of a licensed dentist or physician (§ 801.109).

FDA disagrees with the panel that the class I devices should require premarket notification because they meet the reserved criteria of new section 510(1) of the act. FDA believes that the intended uses of monitoring sounds emanated from the temporomandibular joint and mandibular jaw positions should be exempt from premarket notification. These devices for these intended uses are not of substantial importance in preventing impairment of human health, nor do they present an unreasonable risk of illness or injury.

FDA, however, is proposing that the jaw tracking device and the dental sonography device when used to interpret temporomandibular joint position or sounds for the diagnosis of temporomandibular joint disorder and associated orofacial pain be class II. As noted previously, section 510(m) of the act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA tentatively concludes that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the jaw tracking device and the dental sonography device when used to interpret temporomandibular joint position or sounds for the diagnosis of temporomandibular joint disorder and associated orofacial pain.

IV. Special Controls

FDA has included the special controls that it believes are necessary to provide reasonable assurance of the safety and effectiveness of the devices proposed for class II in the draft guidance document entitled ''Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Guidance for Industry and FDA Reviewers.'' FDA intends this guidance to serve as the special control for these devices, if FDA classifies them in class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document. The draft guidance document sets forth recommendations on 510(k) submissions for the class II devices on device characterization, intended use and indications for use, preclinical and bench testing, device comparison, instructions for use, clinical information, and software validation. The draft guidance document would address the risk of electrical interference by assuring that the 510(k) includes preclinical and bench testing concerning this risk and by assuring that the device labeling includes adequate information for the user to minimize the risk of electrical interference. The guidance document

would address the risk of improper treatment by assuring that the 510(k) includes clinical information on this risks, by assuring that the labeling includes adequate information for the health professional using the device, and by assuring that the manufacturer has properly validated the software. If adopted, following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket nitification for the device would need to address the issues covered in the special control guidance. However, the firm would need to show only that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The class I devices are already subject to the general controls provisions of the act. If FDA finalizes this rule, it would impose no new requirements on manufacturers of class I devices. Manufacturers of class II jaw tracking and dental sonography devices currently are required to submit premarket notifications. The guidance document reflects existing FDA practice in the review of these premarket notifications. FDA expects that manufacturers of cleared class II jaw tracking and dental sonography devices will not have to take any additional action in response to this rule, if FDA finalizes this rule. This rule will help expedite the review process for any new manufacturers of these devices. The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Proposed Implementation Plan

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

IX. Comments

You may submit written or electronic comments regarding this proposal to the Dockets Management Branch (see **ADDRESSES**) by November 12, 2002. You should submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. You may see any comments that FDA receives in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Dental Products Panel Meeting, Transcript and Meeting Minutes, August 4, 1998.

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5. Copper, B. C. and D. D. Rabuzzi, ''Myofacial Pain Dysfunction Syndrome: A Clinical Study of Asymptomatic Subjects,'' *Laryngoscope 94*, January: 68–75, 1984.

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7. Feine, J. S., M. O. Hutchins, and J. P. Lund, ''An Evaluation of the Criteria Used to Diagnose Mandibular Dysfunction With the Mandibular Kinesiograph,'' *The Journal of Prosthetic Dentistry*, 60: 374–380, 1988.

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9. Gay, T., C. N. Bertolami, R. B. Donoff, D. A. Keith, and J. P. Kelly, ''The Acoustical Characteristics of the Normal and Abnormal Temporomandibular Joint,'' *Journal of Oral and Maxillofacial Surgery*, 45: 397–407,1987.

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14. Laskin, D. M. and S. Block, ''Diagnosis and Treatment of Myofacial Pain-Dysfunction (MPD) Syndrome,'' *The Journal of Prosthetic Dentistry*, 56: 75–83, 1986.

15. Laskin, D. M. and C. S. Greene, ''Technological Methods in the Diagnosis and Treatment of Temporomandibular Disorders,'' *International Journal of Technology Assessment in Health Care*, 6: 558–568, 1990.

16. Lederman, K. H., ''Patients With Restored Occlusions. Part I: TMJ Dysfunction Determined by a Pantographic Reproducibility Index,'' *The Journal of Prosthetic Dentistry*, 47: 198–205, 1982.

17. Levitt, S. R. and M. W. McKinney, ''Appropriate Use of Predictive Values in Clinical Decision Making and Evaluating Diagnostic Tests for TMD,'' *Journal of Orofacial Pain*, 8: 298–308, 1994.

18. Lund, J. P., Widmer, C. G., and J. S. Feive, ''Validity of Diagnostic and Monitoring Tests Used for Temporomandibular Disorders,'' *Journal of Dental Research*, 74: 1133–1143, 1995.

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34. Management of Temporomandibular Disorders, National Institutes of Health Technology Assessment Conference Statement, April 29-May 1, pp. 1–31, 1996.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA is proposing to amend 21 CFR part 872 as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 872.2050 is added to subpart B to read as follows:

§ 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 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.

(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; Guidance for Industry and FDA Reviewers.''

3. Section 872.2060 is added to subpart B to read as follows:

§ 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 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.

(b) *Jaw tracking device for interpretation of temporomandibular joint position for the diagnosis of temporomandibular joint disorders and associated orofacial pain*—(1) *Identification.* A jaw tracking device for interpretation of temporomandibular joint position for the diagnosis of temporomandibular joint disorders and associated orofacial pain is a nonpowered or electrically powered device that measures and records anatomical distances and angles to determine the relative position of the mandible in three dimensional space, with respect to the location and position of the maxilla, while at rest and during jaw movement. The device records, displays, and stores information about jaw position. The device interprets jaw position 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 jaw position 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; Guidance for Industry and FDA Reviewers.''

Dated: August 1, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–20499 Filed 8–13–02; 8:45 am]

BILLING CODE 4160–01–S