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

ADRESSES.

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

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

(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,
alter ed, 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.

(i) 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.

(b) 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 Otrokvice, 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–

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, 5650 Fishers Lane, rm.
1061, Rockville, MD 20852. Submit
electronic comments to http://
www.fda.gov/dockets/ecomments.
Safe Medical Devices Act of 1990

premarket notification procedures in

offered devices by means of the

substantially equivalent to previously

require premarket approval. The agency

act, to a predicate device that does not

equivalent, under section 513(i) of the

513(f)(2) of the act, as amended by

I or II; (2) FDA issues an order

rulemaking process. Those devices

automatically by statute (section 513(f)

generally referred to as preamendments
devices under these

procedures.

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 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 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.

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).

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 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,
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. 360(j)(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 precaution for the user to minimize the risk of electrical interference. The guidance document...
would address the risk of improper treatment by assuming that the 510(k) includes clinical information on this risks, by assuming that the labeling includes adequate information for the health professional using the device, and by assuming 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 notification 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 oral 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.


