Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices

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C·D·R·H
Center for Devices and Radiological Health

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Dental Devices Branch
Division of Anesthesiology, Infection Control, General Hospital, and Dental Devices
Office of Device Evaluation

Contains Nonbinding Recommendations

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document and Docket No. 02D-0306. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document was developed as a special control guidance to support the classification into class II of the following devices with the diagnostic intended uses identified below. This guidance is issued in conjunction with a Federal Register notice announcing the classification of these devices.

- Dental sonography devices intended to interpret jaw sounds for the diagnosis of temporomandibular joint disorders and associated orofacial pain.

- Jaw tracking devices intended to interpret mandibular jaw positions relative to the maxilla, for the diagnosis of temporomandibular joint disorders and associated orofacial pain.

However, when these devices are intended only to monitor jaw sounds or positions, they will be classified into class I and will be exempt from premarket notification requirements.1 This guidance does not apply to these class I devices.

Following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket notification for a dental sonography or jaw tracking device will need to address the issues covered in the

[1] Subject to the Limitations to Exemptions, see 21 CFR 872.9.

special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the statutory and regulatory criteria in the manner suggested by the guidance and in your attempt to address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues**" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug & Cosmetic Act (the Act), including the 510(k) requirements described in 21 CFR 807 Subpart E, (2) address the specific risks to health associated with these devices identified in this guidance and, (3) obtain a substantial equivalence determination from FDA prior to marketing the device, unless exempt from the premarket notification requirements of the Act (refer to 21 CFR 807.85).

This special control guidance document identifies the classification regulations and product codes for the dental sonography and jaw tracking devices to which it applies (refer to Section 4 – **Scope)**. In addition, other sections of this special control guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these generic dental sonography and jaw tracking device types and lead to a timely 510(k) review and clearance. This document supplements other agency documents regarding the specific content requirements of a 510(k) submission. You should also refer to CDRH's **Device Advice** http://www.fda.gov/cdrh/devadvice/ and 21 CFR 807.87.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**[2]," a manufacturer may submit a traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a Class II Special Controls Guidance Document has been issued. Manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this guidance document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this Class II Special Controls Guidance Document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 9 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain:

- Description of the device and its intended use. The description should include a complete discussion of the performance specifications and, when appropriate, detailed, labeled

[2] http://www.fda.gov/cdrh/ode/parad510.html

drawings of the device. (Refer to Section 5 for specific information that should be included in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[3]

- Description of device design requirements.

- Identification of the Risk Analysis method(s) used to assess the risk profile in general as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device that FDA has identified.)

- Discussion of the device characteristics that address the risks identified in this Class II Special Controls Guidance Document, as well as any additional risks identified in your risk analysis.

- A brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 7 and 8 of this Class II Special Controls Guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you should either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[4] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.[5] Please note that testing must be

[3] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

[4] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria, and thus differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[5] See Required Elements for a Declaration of Conformity to a Recognized Standard (SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS), http://www.fda.gov/cdrh/ode/reqrecstand.html.

completed before submitting a declaration of conformity to a recognized standard. (Section 514(c)(1)(B) of the Act). For more information, see FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification for this device.

4. Scope

This special control guidance document identifies below the classifications, product codes, and classification identifications for both class I and class II dental sonography and jaw tracking devices. **The guidance only applies to those in class II**.

Class I: Dental Sonography Device for Monitoring

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. 21 CFR 872.2050(a), product code, NFQ.

Class II: Dental Sonography Device for Interpretation and Diagnosis

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. 21 CFR 872.2050(b), product code, NFP.

Class I: Jaw Tracking Device for Monitoring

A jaw tracking device for monitoring mandibular jaw positions relative to the 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. 21 CFR 872.2060(a), product code, NFS.

Class II: Jaw Tracking Device for Interpretation and Diagnosis

A jaw tracking device for interpretation of mandibular jaw positions relative to the maxilla 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. 21 CFR 872.2060(b), product code, NFR.

5. Device Description

We recommend that you identify your device, by regulation and product code and include the following, in addition to the information described above:

- identity of the materials that contact the patient
- critical design and performance specifications and tolerances for the device
- function of the device and of each component of the device
- control and safety mechanisms.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, prior to

submitting your 510(k), to identify any other risks specific to your device. The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this guidance document, or have identified risks additional to those in the guidance, you should provide sufficient detail to support the approach you have used to address that risk.

Class II Dental Sonography Device and Class II Jaw Tracking Device

Identified risk	Recommended mitigation measures
Electromagnetic interference	section 7, 8
Improper treatment	section 8, 9

Dental sonography and jaw tracking devices include parts that are applied to patients. FDA recommends that you evaluate the biocompatibility of the patient-contacting materials in your device. Please refer to the guidance documents entitled Blue Book Memo, G95-1, **Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing",** http://www.fda.gov/cdrh/g951.html. You should select biocompatibility tests appropriate for either intraoral devices, limited duration of contact with intact mucosa, or extraoral devices, limited duration of contact with intact skin, depending on your device design. If your device design includes patient contact with any electrically powered device component, FDA recommends that the device meet the electrical safety requirements of IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995). We recommend that you evaluate your device as described and, for those dental sonography and jaw tracking devices that are class II, document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.20).

7. Pre-clinical and Bench Testing

Device Comparison

FDA recommends that you compare your device and other devices in this device type to show:

- Signal to noise comparison
- Interference factors
- Sensitivity and specificity of instrument readings
- Accuracy of instrument readings.

Software Validation

FDA recommends that you provide documentation of the software validation for all programs associated with the device. FDA guidances, "**Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final**," www.fda.gov/cdrh/ode/57.html and "**Guidance for Off-the-Shelf Software Use in Medical Devices; Final**," www.fda.gov/cdrh/ode/1252.html, contain information about the documentation recommended.

FDA believes the software used in class II dental sonography and jaw tracking devices meets the definition given in these guidances for "major level of concern devices," because they are used in the diagnosis of a condition, which if misdiagnosed, could result in a serious injury to the patient. Therefore, you should provide documentation for "major level of concern" devices.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) encompasses both emissions (interference with other electronic devices) and immunity (interference with device performance created by emissions from other electronic devices). We recommend that you evaluate the EMC of your device as discussed below.

Emissions

EMC testing should demonstrate that the device will not adversely interfere with the performance of other electronic devices, such as active implantable devices, e.g., pacemakers and defibrillators. Testing should include radio frequency (RF) electromagnetic, low frequency magnetic, and conducted emissions.

Immunity

EMC testing should also demonstrate that the device will perform as expected in the presence of other electrical and electronic devices or other sources of electromagnetic disturbance (EMD) in the intended environment of use (*immunity*). The device should operate in an acceptable manner (few EMC standards require operation within specification) during and after exposure to various forms of electromagnetic disturbance. Testing should include:

- electrostatic discharge (ESD)
- radiated RF electromagnetic fields
- electrical fast transients and bursts
- surges
- conducted RF electromagnetic energy
- voltage dips, short interruptions, and voltage variations on power supply input lines
- low-frequency magnetic fields

- quasi-static electric fields.

We recommend that you test your device according to IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) to demonstrate the EMC characteristics of your device.

Interpretation functions of the device

FDA recommends that you describe the pre-clinical testing protocols used to verify the interpretation functions of the device.

8. Clinical Information

In accordance with the Least Burdensome provisions of the FDA Modernization Act of 1997, the agency will avoid requiring clinical studies for new devices unless there is a specific justification for asking for information to support a substantially equivalent determination. FDA believes clinical information is needed to support the intended use, "for the diagnosis of temporomandibular joint disorders and associated orofacial pain." We recommend the clinical information show that a diagnostic endpoint exists and the device can identify and differentiate diseased and healthy patients based on that diagnostic endpoint. Clinical information may consist of studies in the published literature, clinical studies conducted for the premarket submission, or both. For the class II dental sonography and jaw tracking devices, we recommend you provide clinical information demonstrating that the device is able to:

- identify a diagnostic endpoint that is correlated with a disease condition; and

- differentiate the claimed diseased patients from patients not requiring medical intervention, i.e., that sounds and movement patterns of healthy patients can be distinguished from those of patients with temporomandibular joint disorder and associated orofacial pain.

The class I sonography and jaw tracking devices are exempt from the requirements of 21 CFR Part 812 Investigational Device Exemptions (IDE), as long as they meet the criteria set forth in 21 CFR 812.2(c)(3).

FDA believes that the class II sonography and jaw tracking devices addressed by this guidance document are non-significant risk devices, therefore studies of these devices are subject to the abbreviated requirements of 21 CFR 812.2(b).[6] In addition to the requirements of section 21 CFR

[6] Refer to Blue Book Memorandum entitled **Significant Risk And Nonsignificant Risk Medical Device Studies** at http://www.fda.gov/cdrh/d861.html.

812.2(b), sponsors of such trials must comply with the regulations governing institutional review boards (21 CFR Part 56) and informed consent (21 CFR Part 50).

After FDA determines that the device is substantially equivalent, clinical studies conducted in accordance with the indications reviewed in the 510(k), including clinical design validation studies conducted in accordance with the quality systems regulation, are exempt from the investigational device exemptions (IDE) requirements. However, such studies must be performed in conformance with 21 CFR 56 and 21 CFR 50.

9. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).[7]

Instructions for Use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we recommend submitting clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

FDA recommends that the instructions for use include:

- details regarding the methods to be used to interpret jaw sounds, or jaw positions for the diagnosis of temporomandibular joint disorders
- the qualifications of intended users of the device.

Indications for Use

FDA recommends that you provide a clear, concise indications for use statement in the device labeling. It should include the intended patient population for which the device was designed and properly validated.

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[7] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

Warnings

Unless the electromagnetic compatibility of the device has been demonstrated through proper testing, a warning statement should inform users of:

- the potential for the device to interfere with the proper functioning of other devices, including active implantable devices such as pacemakers and defibrillators
- the potential for interference from other electromagnetic products being operated in the immediate vicinity of the device.

The warning section should also identify any patient subpopulations where the diagnostic capability of the device has not been established.

Precautions

Unless clinical evidence establishes the relationship between device output and diagnosis, FDA recommends that you include a precaution that the outputs of these devices are adjunctive to other diagnostic and therapeutic modalities.