Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers

Draft Guidance – Not for Implementation

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U.S. Department Of Health and Human Services
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Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, 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.

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This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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.

- 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. This guidance does not apply to these class I devices.

This guidance will be issued in conjunction with a Federal Register notice announcing the proposal to classify this device type. This guidance is issued for comment purposes only. If the final rule does not classify this device type, this special controls guidance document will be revised.

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 surgical sutures 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 suture 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 21 CFR 807.87 and other agency documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices,** http://www.fda.gov/cdrh/manual/510kprt1.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance**[1]," 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, you should 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 you should include in an Abbreviated 510(k).

1 http://www.fda.gov/cdrh/ode/parad510.html

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

The summary report should 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 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.[2]

- 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

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

the acceptance criteria that you will apply to your test results.[3] (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.[4] Please note that testing must be completed before submitting a declaration of conformity to a recognized standard. (21 USC 514(c)(2)(B)). 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 proposed classifications, product

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3 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).

4 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.

codes, and classification definitions 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

The class I, exempt from premarket notification requirements dental sonography device is an electrically powered device, intended to monitor temporomandibular joint sounds. The device is used to detect and record sounds made by the temporomandibular joint. 21 CFR 862.2050, product code, NFQ.

Class II Dental Sonography Device

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. 21 CFR 862.2050, product code, NFP.

Class I Jaw Tracking Device

The class I, exempt from premarket notification requirements jaw tracking device is a non-powered 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. 21 CFR 862.2060, product code, NFS.

Class II Jaw Tracking Device

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. 21 CFR 862.2060, product code, NFR.

5. Device Description

In addition to the information required above, you should provide:

- 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
Electrical interference or shock	section 7, 8
Improper treatment	section 8, 9

7. Pre-clinical and Bench Testing

Device Comparison

You should 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.

Biocompatibility

You should 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 surface devices intended for limited duration of contact. If *identical* materials are used in a legally marketed device with the same type and duration of patient contact, you may identify the legally marketed device in lieu of performing biocompatibility testing.

Software Validation

You should 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 needed.

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.

Electrical shock

The device should 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).

Interference with pacemaker or other electrical stimulatory devices

Diagnostic and therapeutic medical devices, such as certain types of cardiac pacemakers, may be affected by electrical interference generated by these devices. The isolation of electrical circuitry of these devices from other medical devices should be validated. The device should meet the EMC requirements of *IEC 60601-1-2 (2001): Medical electrical equipment, Part 1: General Requirements for Safety, 2. Collateral standard: Electromagnetic Compatibility - Requirements and Tests.*

Interpretation functions of the device

You should describe provide the pre-clinical testing protocols used to verify the interpretation functions of the device. You should state your acceptance criteria and provide a summary of your results.

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." The clinical information should 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, you should 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.

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).[5]

Instructions for Use

Instructions for use should include information on the methods used to interpret jaw sounds or positions for the diagnosis of temporomandibular joint disorders. Instructions for use should identify the intended users of the device, such as healthcare workers and/or home care patients. Instructions for use should be appropriate for the level of training and education that the intended users may have.

Intended Use and Indications for Use

You should provide a clear, concise intended use statement (21 CFR 801.4) and the specific

5 Although final labeling is not required for 510(k) clearance, final labeling must also 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.

indications for use of the device. You should include the intended patient population in the indications for use.

Contraindications

You should identify any patient population for which the device is not recommended. For example, the device could be contraindicated because there are no data establishing the interpretation of output on a specific patient population. Similarly, the device could be contraindicated in patients with cardiac pacemakers, if there is electromagnetic interference with pacemakers.

Precautions

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. You should include a precaution that the outputs of these devices are adjunctive to other diagnostic and therapeutic modalities.

10. Investigational Device Exemptions

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).

If a clinical study is needed to demonstrate substantial equivalence, the requirements of the IDE regulation (21 CFR 812) will apply to the study. FDA has determined the devices addressed by this guidance document are non-significant risk, and therefore studies of these devices are subject only to the abbreviated requirements of 21 CFR 812.2(b).