Temporary Mandibular Condyle Reconstruction Plate Class II Special Controls Guideline

Guideline for Industry and Food and Drug Administration Staff

Document issued on: December 30, 2013

The draft of this document was issued on: February 7, 2013

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Food and Drug Administration
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Preface

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1. Introduction

The Food and Drug Administration (FDA) has developed this guideline as the special controls to support the reclassification of the temporary mandibular condyle reconstruction plate (TMCRP) from class III to class II (special controls), which has been issued as a final order in the Federal Register. A TMCRP is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

This guideline identifies measures that FDA believes will mitigate the risks to health associated with TMCRPs and provide a reasonable assurance of safety and effectiveness. Firms submitting a 510(k) for a TMCRP must either (1) comply with the particular mitigation measures set forth in the special controls guideline or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

2. Background

FDA believes that these special controls, combined with general controls, are necessary to provide reasonable assurance of the safety and effectiveness of TMCRPs. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, & Cosmetic Act (the FD&C Act), including the premarket notification requirements described in 21 CFR 807 subpart E, (2) address the specific risks to health associated with a TMCRP identified in this guideline, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special controls guideline identifies the classification and product code for the TMCRP. (Please refer to **Section 3 (Scope)**). In addition, the special controls guideline lists the risks to health identified by FDA and describes required measures that, in addition to general controls, address the risks associated with these TMCRPs. This document sets forth criteria that are supplemental to other applicable requirements, including the requirements regarding the specific content of a premarket notification submission (see 21 CFR 807.87). For further information about premarket notification submissions, see the guidance, *Format for Traditional and Abbreviated 510(k)s* (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm08

4365.htm), and the section of CDRH's Device Advice, *Premarket Notification Submission 510(k)* (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm).

FDA also has issued a guidance on the procedure and criteria related to the administrative completeness of 510(k) submissions, *Refuse to Accept Policy for 510(k)s* (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf).

3. Scope

The scope of this document is limited to the device described below.

- **21 CFR 872.4770** – Temporary Mandibular Condyle Reconstruction Plate and with product code **NEI**.

TMCRP is classified as specified in 21 CFR 872.4770 with this identification:

> "A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders."

This generic type of device consists of a bone plate that extends into a condylar head and is attached to the mandible via bone screws. These components are fabricated from materials such as medical grade titanium alloy, stainless steel, and cobalt-chromium alloys.

This generic type of device does **not** include (and the guideline does not address) the following:

- permanent mandibular condyle prostheses (21 CFR 872.3960), which are intended for permanent replacement of the mandibular condyle to articulate within the glenoid fossa in the treatment of temporomandibular joint disorders and are classified as class III devices;
- bone plates for other oral and maxillofacial indications (21 CFR 872.4760); and
- base metal alloys (21 CFR 872.3710).

4. Risks to Health

In Table 1, FDA has identified the risks to health generally associated with the use of the device. The measures to mitigate these identified risks are described in a particular section of this guideline, as indicated in Table 1. Conduct a risk analysis before submitting your 510(k) to identify any other risks specific to the device and include the results of this analysis in your 510(k). If you elect to use an alternative approach to address a particular risk identified in this

document, or have identified risks additional to those in this document, provide sufficient detail to support the approach you have used to address that risk.

Table 1: TMCRP Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Loosening, migration or exposure	Section 5 – Materials and Performance Data Section 8 – Labeling
Mechanical wear of the plate or screws and foreign body reaction	Section 5 – Materials and Performance Data
Structural/mechanical failure	Section 5 – Materials and Performance Data
Migration or thermal injury from magnetic resonance scans	Section 5 – Materials and Performance Data
Corrosion	Section 5 – Materials and Performance Data
Adverse reaction to TMCRP	Section 6 - Biocompatibility
Infection	Section 7 – Sterilization
Degenerative changes to glenoid fossa surfaces	Section 8 – Labeling
Malocclusion, changes in mastication, and contralateral joint	Section 8 – Labeling
User error	Section 8 – Labeling
Transient or chronic pain and facial nerve paresis	Section 8 – Labeling

5. Materials and Performance Data

A. Descriptive Characteristics

Provide a complete description of all components of a TMCRP, including the following:

- materials of composition of all plates, screws, and condylar head components, including identification and/or characterization of any coatings or surface treatments;
- engineering drawings of all plates, screws, and condylar head components;
- a description of the condylar head shape (e.g., spherical, oval, etc.) with dimensions;
- screw dimensions: overall screw length, slot type, core diameter, thread diameter and length, and thread pitch; and
- plate dimensions: thickness, width, length, number of screw holes or slot dimensions, and screw hole diameter.

B. Consensus Standards

A TMCRP device is to conform to the following FDA-recognized standards or an equivalent method:

1) Materials of composition

- *ISO 5832, "Implants for surgery -- Metallic materials" (Parts 1-6, 9, 11, and 12).*

2) Performance specifications for screws and bone plates

- *ASTM F 543-07e1, "Standard Specification and Test Methods for Metallic Medical Bone Screws," 2007.*
- *ASTM F 382-99 (Reapproved 2008)e1, "Standard Specification and Test Method for Metallic Bone Plates," 2009.*

C. Performance Data

Provide the following engineering performance data for the TMCRP device, in accordance with *ASTM F 543-07e1* and *ASTM F 382-99 (Reapproved 2008)e1*, or an equivalent method:

- Screw axial pull out load (N)
- Screw insertion torque (N-m)
- Screw torsional yield strength (N-m)
- Bone plate bending strength (N-m) – static
- Bone plate bending stiffness (N/mm) – static
- Fatigue testing on four-point bending configuration showing progressive load (N) to failure and cycles completed to failure load
- M-N diagram -- maximum applied bending moment verses number of cycles to a specified failure point. Identify the failure mode and report of any screw loosening.
- Corrosion resistance testing (in accordance with *ASTM F 897-02 (Reapproved 2007), "Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws," 2007*)

D. Magnetic Resonance (MR) Compatibility

In order to address risks associated with MR scans, firms must either demonstrate safety of their devices in MR environments or, alternatively, include in their device's labeling a warning indicating that their device has not been tested for MR compatibility and the safety has not been determined. For FDA's current thinking on demonstrating safety of implantable medical devices in MR environments, see the Guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, August 21, 2008 (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107705.htm).

6. Biocompatibility

Conduct biocompatibility testing for the TMCRP device in accordance with the following FDA-recognized standard or by an equivalent method:

- *ISO 7405:1997(E), "Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry—Test methods for dental materials," 2008.*

If, however, the materials of composition of the new device have already been demonstrated to be biocompatible for the same indication and type and duration of tissue contact, either by reference

to a predicate device or evidence present in the literature, you may support the biocompatibility of the new device by identifying the predicate device or citing to the literature in lieu of performing biocompatibility testing. If the new device features new materials/coatings, includes new technological features, or introduces new indications, conduct biocompatibility testing as identified above. Also, contact FDA to determine if additional performance testing is needed to support the biocompatibility of the device.

7. Sterilization

Provide the following information if the TMCRP device is provided sterile:

- identification of sterilization method;
- identification of validation method for the sterilization cycle (e.g., ISO 11137, ISO 11135-1:1994, etc.);
- sterility assurance level (SAL) of minimum of 10^{-6};
- radiation type and dose (kGy) or sterilant residuals (mg EtO/in 24 hrs), whichever is applicable; and
- a description of the packaging used to maintain sterility.

If the new device is provided non-sterile and labeled for sterilization by the end user, instructions and labeling of the TMCRP device must include a recommended sterilization cycle. The recommended cycle must be validated prior to marketing and include technically feasible parameters (e.g., time, temperature, load characteristics, and drying time for steam sterilization (e.g., autoclave)), that will enable the user to achieve a SAL of 10^{-6}.

For FDA's current thinking on sterilization, see *Guidance for Industry and FDA Staff: Updated 510(k) Sterility Review Guidance K90-1*, August 2002[1] (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072790.pdf). For FDA's current thinking on labeling and validation methods for processing of medical devices, see *Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, April 1996[2] (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf).

[1] The version of this guidance that was published in August 2002 is the effective version, but an updated version was published in draft on December 12, 2008. This updated version, when final, will supersede the 2002 version and represent FDA's current thinking on this topic. The updated version can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109884.htm.

[2] The version of this guidance that was published in April 1996 is the effective version, but an updated version was published in draft on May 2, 2011. This updated version, when final, will supersede the 1996 version and represent FDA's current thinking on this topic. The updated version can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm252999.htm.

8. Labeling[3]

The 510(k) submission must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e) and 21 CFR part 801.

The labeling described in this section is not intended to be exhaustive but represents some basic information that is to be included as part of the TMCRP device labeling provided to surgeons and patients. Supplement this labeling with information sufficient to inform surgeons of the limitations and proper use of the device and to enable them to achieve satisfactory results. This may include instructions for patient selection, component selection, and site preparation, proper placement of the device, site closure, and follow-up patient care.

Because TMCRP are prescription use devices, in accordance with 21 CFR 801.109(b)(1), labeling must include the statement "Caution: Federal law restricts this device to sale by or on the order of a physician."

8.1 Professional Labeling

Include professional labeling addressing the contraindications, warnings, precautions, and general risks associated with the device, as required by 21 CFR 801.109. This includes the following:

A. Contraindications

Include contraindications for use of the device by:

- patients with temporomandibular joint (TMJ) disorders or with traumatic injuries to the condyle;
- patients with metal allergies and foreign body sensitivity; and
- patients with limited blood supply or inadequate bone at the site.

B. Warnings

Include these warnings:

- TMCRPs are intended only for temporary fixation (less than 24 months) and only in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for permanent implantation or for treatment of patients with TMJ disorders.

- Single use only. Do not re-use.

- Avoid direct metal to bone contact between the condylar component and the natural glenoid fossa. A soft tissue interface should be used between these surfaces.

[3] Final labeling must comply with the requirements of 21 CFR part 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 criteria in this guideline are consistent with the requirements of part 801.

- Do not use plates, screws, and other components of dissimilar metals together at the implant site.

C. Precautions
Include these precautions:

- Failure to use the appropriate components, provide rigid fixation, and maintain an adequate blood supply may result in implant loosening, bending, or fracture of the implant and/or bone.

- Postoperative care should consist of a soft-food diet until bony healing occurs (6-10 weeks). Afterwards, normal biting forces associated with an unrestricted diet may not be tolerated with this implant.

D. General Risks
Include a discussion of the general risks associated with the device, including the following:

- implant loosening, migration, or exposure;
- degenerative changes to the natural articulating surfaces;
- malocclusion and changes in mastication and the contralateral joint;
- foreign body reaction;
- loss of implant integrity;
- transient or chronic pain/ facial nerve paresis; and
- infection.

8.2 Patient Labeling

Patient labeling is to be included and the following statements and/or principles must be addressed:

- Duration of implantation: The temporary mandibular condyle reconstruction plate is intended for temporary use (defined as less than 24 months) only. It is not intended to permanently reconstruct the TMJ. It is not intended for permanent treatment of TMJ disorders.

- Instructions to the patient regarding the following aspects:

    - Notification that normal biting forces may not be tolerated with this implant.
    - How to appropriately avoid trauma to the implant site.
    - Discussion with the surgeon about an appropriate diet to follow after implantation of the device.

- Inclusion of possible complications and/or adverse reactions from the use of this implant.

- The patient should be instructed how to report any complications or unusual changes to the surgeon or FDA.

- A glossary of medical terminology.

For FDA's current thinking on development of patient labeling, refer to *Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers*, April 19, 2001 (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070801.pdf).