Background

On October 22, 2012, the FAA published in the **Federal Register** a NPRM to remove a segment of VOR Federal airway V–595 due to the planned decommissioning of the Portland, OR, VOR/DME (77 FR 64444). No comments were received.

The NPRM would have terminated V–595 at the HARZL navigation fix, which is approximately 29 NM southeast of the Portland VOR/DME. Subsequent to the publication, further study showed that mountainous terrain in the area would limit the service volume of the Deschutes, OR, VORTAC to a degree that the Deschutes VORTAC could not be used to identify the entire length of the proposed segment between Deschutes and the HARZL fix. In addition, the decommissioning of the Portland VOR/DME would require raising the IFR minimum enroute altitude (MEA) along that segment to an unusable height.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to further modify the description of VOR Federal airway V–595. Instead of removing that segment of V–595 between the Portland, OR, VOR/DME and the HARZL fix, as originally proposed, the FAA is now proposing to remove the entire V–595 segment between the Deschutes VORTAC and the Portland VOR/DME. Consequently, the amended V–595 would extend only between the Rogue Valley, OR, VORTAC and the Deschutes VORTAC. This action is necessary because the Portland, OR, VOR/DME, which currently serves as the northern end point of the route, is scheduled to be decommissioned. Further, due to high terrain issues, the Deschutes VORTAC service volume is not adequate to support the originally proposed segment between Deschutes and the HARZL fix. By separate rulemaking action, the FAA is proposing to establish new area navigation routes (T-routes) in the area.

Since this change expands the scope of the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

VOR Federal airways are published in paragraph 6010, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document would be subsequently published in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies an Oregon route structure as required to preserve the safe and efficient flow of air traffic.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9W, Airspace Designations and Reporting Points, Dated August 8, 2012 and effective September 15, 2012, is amended as follows:

* * * * *

Paragraph 6010 Domestic VOR Federal airways.

V–595 [Amended]

From Rogue Valley, OR, to Deschutes, OR.

Issued in Washington, DC, on January 31, 2013.

Alan Wilkes,

Acting Manager, Airspace Policy and ATC Procedures Group.

[FR Doc. 2013–02736 Filed 2–6–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2012–N–1239]

Dental Devices; Reclassification of Temporary Mandibular Condyle Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed order to reclassify temporary mandibular condyle prosthesis, a preamendments class III device, into class II (special controls), and rename the device ''temporary mandibular condyle reconstruction plate.'' FDA is also issuing the draft special controls guideline, ''Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate,'' which sets forth the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: Submit either electronic or written comments on this proposed order or on the draft guideline by May 8, 2013. See section XIII of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–1239, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–1239. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1615, Silver Spring, MD 20993, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting 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(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (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.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (DC Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (DC Cir. 1985); *Contact Lens Association* v. *FDA,* 766 F.2d 592 (DC Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application (PMA). (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to temporary mandibular condyle prosthesis, and therefore, has met this requirement under section 513(e)(1) of the FD&C Act. As explained further in section II of this document, a meeting of a device classification panel

described in section 513(b) of the FD&C Act took place in 1997 to discuss whether temporary mandibular condyle prosthesis should be reclassified or remain in class III, and the panel recommended that the device be reclassified into class II because there was sufficient information to establish special controls. FDA is not aware of new information since the 1997 panel that would provide a basis for a different recommendation or findings.

FDAMA added section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Device

In 1994, FDA issued a final rule that classified all mandibular condyle prostheses into class III, based on the recommendation of a Dental Products Panel (the Panel) meeting on February 11, 1993 (59 FR 65475; December 20, 1994). In response to a petition dated April 30, 1996 (FDA–1996–P–0253), FDA considered a distinction between temporary and permanent mandibular condyle prostheses and held a February 12, 1997 meeting of the Panel. The Panel recommended that mandibular condyle prostheses indicated for temporary reconstruction of the mandibular condyle in tumor resection patients be reclassified from class III to class II with special controls, include labeling for temporary use not to exceed 2 years, and have patient registries. Based on its review of the data and information contained in the April 30, 1996, petition, the Panel believed that special controls, in addition to general controls, were necessary to provide a reasonable assurance of safety and effectiveness of these devices in patients who have undergone resective procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle and mandibular bone. On December 30, 1998, FDA issued a final rule calling for PMAs under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) for permanent mandibular condyle prostheses, and simultaneously announced its intention to reclassify, in accordance with the Panel's recommendations, mandibular condyle prosthesis for temporary reconstruction following surgical ablation of malignant and benign tumors (63 FR 71743).

In 2009, FDA published an order for the submission of information on mandibular condyle prostheses indicated for temporary reconstruction (74 FR 16214; April 9, 2009). In response to that order, FDA received information from several device manufacturers who recommended that these devices be reclassified to class II. The manufacturers stated that the safety and effectiveness of these devices may be reasonably assured by bench testing, biocompatibility testing, sterility testing, expiration date testing, labeling, and performance standards.

On the basis of its review and the recommendations from the Panel and industry, FDA now believes that the use of temporary mandibular condyle prostheses for patients who have undergone any resective surgical procedure requiring removal of the mandibular condyle and mandibular bone does not present a potential unreasonable risk of illness and injury, and that special controls, in addition to general controls, are necessary to provide reasonable assurance of the safety and effectiveness of the device. Although the Panel recommended that class II was appropriate for plates indicated in tumor resection cases only, FDA believes that the special controls proposed in this document are appropriate to provide reasonable assurance of safety and effectiveness for temporary reconstruction of the mandibular condyle in patients who have undergone any resective surgical procedures requiring removal of the mandibular condyle and mandibular bone.

III. Device Description

A mandibular condyle prosthesis is a device that is intended to be implanted in the human jaw to replace the mandibular condyle and to articulate within a glenoid fossa.

FDA is proposing this order to create a new classification for the temporary mandibular condyle prosthesis and rename it the temporary mandibular condyle reconstruction plate (TMCRP) to distinguish it from permanent mandibular condyle prosthesis. TMCRP devices will be identified as:

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.

The new classification will be placed under 21 CFR part 872, subpart E—Surgical Devices, as a TMCRP is not intended to permanently replace the function of the mandibular condyle.

IV. Proposed Reclassification

FDA is proposing that temporary mandibular condyle prosthesis be reclassified from class III to class II with a special controls guideline. FDA is also proposing to create a separate classification for these devices, to rename them temporary mandibular condyle reconstruction plate, and place them under 21 CFR part 872, subpart E—Surgical Devices, to differentiate them from permanent mandibular condyle prostheses and clarify that these devices are intended as temporary devices and not permanent replacements of the mandibular condyle. FDA believes that these devices can be utilized 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.

FDA has considered TMCRPs in accordance with the reserved criteria and determined that these devices require premarket notification. The Agency does not intend to exempt this proposed class II device from premarket notification (section 510(k) of the FD&C Act) submission as provided for under section 510(m) of the FD&C Act.

V. Risks to Health

After considering the information from the reports and recommendations of the Panel for the classification of these devices along with information submitted in response to the section 515(i) order and any additional information that FDA has at its disposal, FDA has identified and evaluated the risks to health associated with the use of TMCRPs. The Panel had identified these risks to health for all mandibular condyle prostheses in a February 11, 1993, meeting; FDA believes that the risks listed in this document are applicable to TMCRPs, a subset of mandibular condyle prostheses, and that these concerns are still relevant today.

- *Loosening, migration, or exposure.* TMCRP screws or plates may loosen if not placed properly. A loose plate can also lead to migration or exposure of the plate or screws through the skin.
- *Mechanical wear of the plate or screws and foreign body reaction.* Some materials used in the construction of a TMCRP may wear and release particles that may result in a foreign body reaction.

• *Structural/mechanical failure.* A TMCRP may loosen, bend, or fracture and result in a structural or mechanical failure of the plate if not placed properly or used longer than intended.

• *Migration or thermal injury from magnetic resonance scans.* A TMCRP is composed of metals. Certain metallic materials that may be used for a TMCRP can be induced to displace or heat up in the presence of a magnetic field, such as is found in magnetic resonance scans.

• *Corrosion.* A TMCRP is composed of metals. Some materials to be used for a TMCRP may corrode, which can lead to failure and adverse tissue reaction.

• *Adverse reaction to a TMCRP.* Placement of a TMCRP may result in an adverse reaction in certain individuals who may be hypersensitive or allergic to the materials of composition of the TMCRP.

• *Infection.* Placement of a TMCRP may result in a postoperative infection due to the surgical procedure or if the plate or screws have not been sterilized appropriately.

• *Degenerative changes to the glenoid fossa surfaces.* A TMCRP may cause degeneration of the opposing bone, which is an inherent risk of a metal-on-bone joint.

• *Malocclusion, changes in mastication and contralateral joint.* A TMCRP may cause an uneven bite, resulting in malocclusion and potential changes in the contralateral joint, which is a unique risk of a bilateral joint.

• *User error.* A TMCRP may be misused if placed incorrectly or if inappropriately used as a permanent prosthesis rather than a temporary reconstruction plate.

• *Transient or chronic pain and facial nerve paresis.* Placement of a TMCRP may cause transient or chronic pain or nerve paresis associated with changes in jaw structure and function as a result of the surgical procedure.

VI. Summary of Reasons for Reclassification

FDA believes that TMCRPs should be reclassified into class II because special controls, in addition to general controls, are necessary to provide reasonable assurance of the safety and effectiveness of the devices. In addition, there is now sufficient information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with sections 513(e) and 515(i) of the FD&C Act and 21 CFR 860.130, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this preamendments class III device into class II. The new information includes the history of use of the device and the relative absence of adverse events reports despite the longstanding use of these devices, as discussed in the recommendations for reclassification from the device industry (available in docket FDA–2009–M–0101 at *http://www.regulations.gov*) and the February 12, 1997, Panel. The classification recommendations from the device industry recommend that FDA reclassify these devices to class II based on their history of use without evidence of serious adverse events and the ability of preclinical data to provide predictive performance information. These companies cite their own history of use, their own preclinical testing, and relevant peer-reviewed literature that provide evidence that TMCRPs are effective for temporary reconstruction of the mandible and not associated with complications. (Ref. 1) The Panel also recommended reclassification to class II for these devices and believed that special controls, in addition to general controls, would provide a reasonable assurance of safety and effectiveness for these devices. (Ref. 2) FDA believes that this information constitutes sufficient evidence to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V of this document, which are known surgical risks, and that these special controls in addition to the general controls will provide a reasonable assurance of safety and effectiveness for TMCRPs. Although the Panel only recommended that class II was appropriate for plates indicated in tumor resection cases only, FDA believes that the proposed special controls are appropriate to provide reasonable assurance of safety and effectiveness for temporary reconstruction of the mandibular condyle in patients who have undergone any resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. Other clinical instances that may result in mandibular resection include certain traumas, osteoradionecrosis, bisphosphonate-induced osteonecrosis, and osteomyelitis. FDA believes that the risks of using TMCRPs in these instances are the same as the risks in tumor resection cases, and therefore the identified special controls can provide a reasonable assurance of safety and effectiveness for TMCRPs in the following indications: when used 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.

VIII. Proposed Special Controls—Related Document

FDA believes that the measures set forth in the special controls guideline ''Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate'' are necessary, in addition to general controls, to mitigate the risks to health described in section V in this document. As seen in the following table, the special controls set forth in the guideline for this device address each of the identified risks.

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.

TABLE 1—TMCRP RISKS AND MITIGATION MEASURES—Continued

Identified risk	Mitigation measure
Transient or chronic pain and facial nerve paresis	Section 8—Labeling.

If this proposed order is finalized, TMCRPs will be reclassified into Class II. As discussed below, the reclassification will be codified in 21 CFR 872.4770. Firms submitting a 510(k) for a TMCRP will need either to (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 alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. Adherence to the criteria in the guideline, when finalized, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the devices.

IX. Electronic Access to the Special Controls Guideline

Persons interested in obtaining a copy of the draft guideline may do so by using the Internet. A search capability for all Center for Devices and Radiological Health guidelines and guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* The guideline is also available at *http://www.regulations.gov.*

To receive ''Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1799 to identify the guidance you are requesting.

X. 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.

XI. Paperwork Reduction Act of 1995

This proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XII. Clarifications to Special Controls Guidelines

This special controls guideline reflects changes the Agency is making to clarify its position on the binding nature of special controls. The changes include referring to the document as a ''guideline,'' as that term is used in section 513(a) of the FD&C Act, which the Secretary has developed and disseminated to provide a reasonable assurance of safety and effectiveness for class II devices, and not a ''guidance,'' as that term is used in 21 CFR 10.115. The guideline also clarifies that firms will need either to (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. Finally, the guideline uses mandatory language to emphasize that firms must comply with special controls to legally market their class II devices. These revisions do not represent a change in FDA's position about the binding effect of special controls, but rather are intended to address any possible confusion or misunderstanding.

XIII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

XIV. Comments

Interested persons may submit either electronic comments regarding this document or the associated Special Controls guideline to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

XV. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously promulgated regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, pursuant to section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in 21 CFR 872.3960 related to the classification of TMCRPs as Class III devices and to codify the reclassification of TMCRPs into Class II.

XVI. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Carlson, E.R., Disarticulation Resections of the Mandible: A Prospective Review of 16 Cases. *Journal of Oral and Maxillofacial Surgery,* vol. 60, pp. 176–181, 2002.

2. Food and Drug Administration, Dental Products Advisory Panel Meeting Transcript, February 12, 1997; *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=168.*

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, it is proposed that 21 CFR part 872 be amended 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 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

■ 3. Section 872.4770 is added to subpart E to read as follows:

§ 872.4770 Temporary mandibular condyle reconstruction plate.

(a) *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.

(b) *Classification.* Class II (special controls). The special controls is FDA's guideline, ''Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate.'' See § 872.1(e) for the availability of this guidance document.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–02688 Filed 2–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 226

Osage Negotiated Rulemaking Committee

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Meetings.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, the U.S. Department of the Interior, Bureau of Indian Affairs, Osage Negotiated Rulemaking Committee, will meet as indicated in the **DATES** section of this document.

DATES: *Meetings:* The meetings will be held as follows: *February:* Monday, February 25, 2013, from 8 a.m. to 3:30 p.m.; Tuesday, February 26, 2013, from 8 a.m. to 6 p.m.; and Wednesday, February 27, 2013, from 8 a.m. to 6 p.m. *March:* Wednesday, March 13, 2013, from 8 a.m. to 6 p.m. and Thursday, March 14, 2013, from 8 a.m. to 6 p.m.

ADDRESSES: *February Meeting:* Wah Zha Zhi Cultural Center, 1449 W. Main, Pawhuska, Oklahoma 74056; *March Meeting:* Osage Casino Event Center, 951 W. 36 Street North, Tulsa, Oklahoma 74127.

FOR FURTHER INFORMATION CONTACT: Mr. Eddie Streater, Designated Federal Officer, Bureau of Indian Affairs, Wewoka Agency, P.O. Box 1540, Seminole, OK 74818; telephone (405) 257–6250; fax (405) 257–3875; or email *osageregneg@bia.gov.* Additional Committee information can be found at: *http://www.bia.gov/osageregneg.*

SUPPLEMENTARY INFORMATION: On October 14, 2011, the United States and the Osage Nation (formerly known as the Osage Tribe) signed a Settlement Agreement to resolve litigation regarding alleged mismanagement of the Osage Nation's oil and gas mineral estate, among other claims. As part of the Settlement Agreement, the parties agreed that it would be mutually beneficial ''to address means of improving the trust management of the Osage Mineral Estate, the Osage Tribal Trust Account, and Other Osage Accounts.'' Settlement Agreement, Paragraph 1.i. The parties agreed that a review and revision of the existing regulations is warranted to better assist the Bureau of Indian Affairs (BIA) in managing the Osage Mineral Estate. The parties agreed to engage in a negotiated rulemaking for this purpose. Settlement Agreement, Paragraph 9.b. After the Committee submits its report, BIA will develop a proposed rule to be published in the **Federal Register.**

Meeting Agenda: February: Present and review specific proposed changes to or additions to 25 CFR part 226 in the following categories: General/Definitions, Rents, Royalties & Reporting, Operations, Surface Issues, Bonds, Pentalies & Enforcement. *March:* Follow-up discussions and committee decisions on specific proposed changes to or additions to 25 CFR part 226 in the following categories: General/Definitions, Rents, Royalties & Reporting, Operations, Surface issues, Bonds, Penalties & Enforcement. The final agenda will be posted on *www.bia.gov/osagenegreg* prior to each meeting.

Public Input: All Committee meetings are open to the public. Interested members of the public may present, either orally or through written comments, information for the Committee to consider during the public meeting. Written comments should be submitted, prior to, during, or after the meeting, to Mr. Eddie Streater, Designated Federal Officer, preferably via email, at *osagenegneg@bia.gov,* or by U.S. mail to: Mr. Eddie Streater, Designated Federal Officer, Bureau of Indian Affairs, Wewoka Agency, P.O. Box 1540, Seminole, OK 74818. Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record.

Individuals or groups requesting to make oral comments at the public Committee meeting will be limited to 5 minutes per speaker. Speakers who wish to expand their oral statements, or those who had wished to speak, but could not be accommodated during the public comment period, are encouraged to submit their comments in written form to the Committee after the meeting at the address provided above. There will be a sign-up sheet at the meeting for those wishing to speak during the public comment period.

The meeting location is open to the public. Space is limited, however, so we strongly encourage all interested in attending to preregister by submitting your name and contact information via email to Mr. Eddie Streater at *osageregneg@bia.gov.* Persons with disabilities requiring special services, such as an interpreter for the hearing impaired, should contact Mr. Streater at (405) 257–6250 at least seven calendar days prior to the meeting. We will do our best to accommodate those who are unable to meet this deadline.