to agency procedure and practice and, thus, is not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, these regulations are not a ''rule'' as defined by the Regulatory Flexibility Act, 5 U.S.C. 601(2), and no initial or final regulatory flexibility analysis is required.

VI. Paperwork Reduction Act

The Bureau has determined that the regulations in this subpart do not impose any new recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would constitute collections of information requiring approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects in 12 CFR Part 1081

Administrative practice and procedure, Banking, Banks, Consumer protection, Credit, Credit unions, Law enforcement, National banks, Savings associations, Trade practices.

Authority and Issuance

For the reasons set forth above, the interim final rule amending 12 CFR part 1081 published at 78 FR 59163, September 26, 2013, is adopted as a final rule without change.

Dated: June_10, 2014.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2014–14228 Filed 6–17–14; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2012–N–0677]

Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the blade-form endosseous dental implant, a preamendments class III device, into class II (special controls). On its own initiative, based on new information, FDA is revising the classification of blade-form endosseous dental implants.

DATES: This order is effective July 18, 2014.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283, *michael.ryan@fda.hhs.gov*.

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 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism 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) of the FD&C Act 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 (D.C. 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) of the FD&C Act must be ''valid scientific evidence,'' as defined in section 513(a)(3) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Manufacturers Association* v. *FDA,* 766

F.2d 592 (D.C. 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 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.

II. Regulatory History of the Device

FDA published a proposed order to reclassify this device in the **Federal Register** of January 14, 2013 (78 FR 2647) (the ''proposed order''). As discussed in the proposed order, the Agency originally issued a final rule classifying all endosseous dental implants (without distinguishing based on geometry) into class III (52 FR 30082, August 12, 1987). After later consideration by a reclassification panel, root-form endosseous dental implants were reclassified into class II in a final rule issued on May 12, 2004 (69 FR 26302), but blade-form endosseous dental implants remained in class III.

After consideration of available information on blade-form endosseous dental implants, the proposed order indicated that FDA believed these devices could also be down classified to class II, subject to the identified special controls. As required by section 513(e)(1) of the FD&C Act, on July 18, 2013, FDA also convened a meeting of the Dental Products Panel (the Panel) to consider the existing valid scientific evidence to support reclassification of blade-form endosseous dental implants into class II.

The Panel discussed and agreed that the risks to health for this device were adequately captured as presented by FDA. The Panel deliberations included discussion of whether the risk of bone loss is higher for blade-form dental implants as compared to root-form dental implant devices. The Panel also discussed the technique-sensitive nature of this device and expressed a concern that additional training, which may not be found in the current curriculum for dental schools, is needed prior to the use of this device to address the identified risks to health.

The Panel agreed that the proposed special controls were reasonable to mitigate the identified risks to health but recommended the device labeling include specific patient selection criteria and recommendations for training and education requirements for clinicians using this device. The Panel recommended that companies marketing this device ensure that device-specific training is available to clinicians. The Panel also recommended clinical data as a special control for the purpose of capturing failure rates and adverse event detection.

The special controls as previously proposed by FDA included documented clinical experience for effective use and observed adverse events which addresses the recommendations for patient selection criteria, and failure rate and adverse event detection. Additionally, the special controls include patient labeling which must contain instructions for reporting complications. The patient labeling will also address the concern for failure rate and adverse event detection. To address the Panel's concern related to recommendations for training and education requirements, FDA has added a special control for the device labeling to include qualifications and training requirements for clinicians using this device.

The Panel concluded that general controls alone are not sufficient due to the identified risks to health; however, special controls, in combination with the general controls, can be sufficient to assure the safety and effectiveness of blade-form endosseous dental implants. The Panel agreed that this device should be reclassified into class II (special controls).

III. Public Comments in Response to the Proposed Order

In response to the proposed order, FDA received two comments from practicing clinicians. Both of the comments supported reclassification of the devices into class II, and described positive clinical experience regarding the safety and effectiveness of the device. FDA agrees with the comments.

IV. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the preamble to the proposed order. FDA is issuing this final order to reclassify the blade-form endosseous dental implant from class III to class II and to establish special controls. Following the effective date of this final order, firms marketing blade-form endosseous dental implants will need either to: (1) Comply with the particular mitigation measures set forth in the special controls 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.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of blade-form endosseous implants; and therefore, this device type is not exempt from premarket notification requirements.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other 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 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR 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.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued 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, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in 21 CFR 872.3640 related to the classification of blade-form endosseous implants as class III devices and codifying the reclassification of blade-form endosseous into class II.

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, 21 CFR part 872 is 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 872.3640 is amended by revising paragraph (a) and (b)(2) to read as follows:

§ 872.3640 Endosseous dental implant.

(a) *Identification.* An endosseous dental implant is a prescription device made of a material such as titanium or titanium alloy that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) * * *

(2) *Classification.* Class II (special controls). The device is classified as class II if it is a blade-form endosseous dental implant. The special controls for this device are:

(i) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use;

(ii) Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;

(iii) Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;

(iv) The device must be demonstrated to be biocompatible;

(v) Sterility testing must demonstrate the sterility of the device;

(vi) Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;

(vii) Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, relevant precautions and warnings based on the clinical use of the device, and qualifications and training requirements for device users including technicians and clinicians;

(viii) Patient labeling must contain a description of how the device works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and

(ix) Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Dated: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14216 Filed 6–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9669]

RIN 1545–BM25

Participation of a Person Described in Section 6103(n) in a Summons Interview Under Section 7602(a)(2) of the Internal Revenue Code

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations modifying regulations promulgated under section 7602(a) of the Internal Revenue Code relating to administrative summonses. Specifically, these temporary regulations clarify that persons with whom the IRS or the Office of Chief Counsel (Chief Counsel) contracts for services described in section 6103(n) and its implementing regulations may be included as persons designated to receive summoned books, papers, records, or other data and to take summoned testimony under oath. These temporary regulations may affect taxpayers, a taxpayer's officers or employees, and any third party who is served with a summons, as well as any other person entitled to notice of a summons. The text of these temporary regulations serves as the text of the proposed regulations (REG–121542–14) set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 18, 2014.

Applicability Date: For date of applicability, see paragraph (d) of this temporary regulation.

FOR FURTHER INFORMATION CONTACT: A M Gulas at (202) 317–6834 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

These temporary regulations amend Procedure and Administration Regulations (26 CFR part 301) promulgated under section 7602 of the Internal Revenue Code. These temporary regulations make clear that persons described in section 6103(n) and Treas. Reg. § 301.6103(n)–1(a) with whom the IRS or Chief Counsel contracts for services may receive books, papers, records, or other data summoned by the IRS and take testimony of a person who the IRS has summoned as a witness to provide testimony under oath. While IRS officers and employees remain responsible for issuing summonses and developing and conducting examinations, the temporary regulations clarify that contractors are permitted to participate fully in a summons interview. Full participation includes, but is not limited to, receipt, review, and use of summoned books, papers, records, or other data, being present during summons interviews, questioning the person providing testimony under oath, and asking a summoned person's representative to clarify an objection or an assertion of privilege.