4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2014-N-1243]

Dental Devices; Reclassification of Salivary Stimulatory System, To Be Renamed Electrical Salivary Stimulator System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify salivary stimulatory system, a class III device, into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes will provide a reasonable assurance of safety and effectiveness of the device. The Agency is proposing to rename the device "electrical salivary stimulatory system."

DATES: Submit either electronic or written comments by [INSERT 90 DAYS AFTER DATE OF PUBLICATION IN FEDERAL REGISTER]. Please see section IX 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 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 way:

- Mail/Hand delivery/Courier (for paper 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 Docket No. FDA-2014-N-1243 for this rulemaking. 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 section X 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, 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, michael.ryan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background--Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, 21 U.S.C. 301 et seq., establishes 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).

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)(1) 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).

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

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 regulatory authority (see Bell v. Goddard, 366 F.2d 177, 181 (7th Cir. 1966); Ethicon, Inc. v. FDA, 762 F. Supp. 382, 388-391 (D.D.C. 1991)), or in light of changes in "medical science" (Upjohn v. Finch, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the "new

information" to support reclassification under 513(f)(3) 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 Mfrs. Assoc. 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 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 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 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, 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 and the Device Description

A salivary stimulatory system is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. A salivary stimulatory system is an intraoral device intended to stimulate a relative increase in saliva production.

III. Proposed Reclassification and Summary of Reason for Reclassification

FDA is proposing to reclassify these devices from class III into class II because sufficient information exists to establish special controls that can provide a reasonable assurance of the device's safety and effectiveness. FDA believes that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness.

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify this postamendments class III device into class II (special controls). FDA believes that there is sufficient information available to FDA through FDA's accumulated experience with these devices from review submissions, knowledge of similar devices, peer-reviewed literature, and the manufacturer's petition to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in the next section.

FDA is proposing to identify the salivary stimulatory system under the new name of "electrical salivary stimulator system" to distinguish it from other devices that stimulate saliva flow via non-electrical means. Under this proposed order, if finalized, the electrical salivary stimulatory system device will be a prescription device restricted to patient use only upon the authorization of a dental practitioner or physician licensed by law to administer or use the device. (Proposed 21 CFR 872.5560(a); see 21 CFR 801.109 (Prescription devices.).) Prescription-use restrictions are a type of general control defined in section 513(a)(1)(A)(i) of the FD&C Act. The labeling of the device must bear all information required for the safe and effective use of prescription devices as outlined in § 801.109.

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 device. For this type of device FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit FDA a premarket notification prior to marketing the device.

IV. Risks to Health

After considering the information available to FDA through review submissions, the manufacturer's petition, peer-reviewed literature, and knowledge of similar devices, FDA determined that the potential risks to health associated with the use of electrical salivary stimulatory systems are as follows:

- Hazards caused by electrical equipment--electrical salivary stimulatory systems have the potential to cause electrical shocks, thermal burns, and other hazards to a patient;
- hazards caused by electromagnetic interference and electrostatic discharge--electrical salivary stimulatory systems have the potential to cause electromagnetic interference or electrostatic discharge that can negatively affect the performance of the system or other electrical equipment in the vicinity of the system;
- damage to intraoral tissue or dentition--devices that malfunction or are poorly designed may damage intraoral tissue such as the gingiva or tongue or a patient's dentition; and
- adverse tissue reaction--devices with non-biocompatible materials may cause intraoral tissue infection, inflammation, irritation, or allergic reactions.

V. Summary of Data Upon Which the Reclassification Is Based

FDA has considered and analyzed the following information: A search of the Agency's Manufacturer and User Facility Device Experience (MAUDE) database, which shows no adverse events for electrical salivary stimulatory systems; data contained in PMAs approved 6 or more years before the date of this proposal (reviewed under section 520(h)(4) of the FD&C Act, also known as the 6-year rule); and a review of transcutaneous electrical nerve stimulators, which are similar devices technologically, and are currently regulated as class II devices.

VI. Proposed Special Controls

FDA tentatively concludes that the following special controls, together with general controls, are sufficient to mitigate the risks to health described in section IV:

- The design characteristics of the device must ensure that the geometry, material composition, and electrical output characteristics are consistent with the intended use;
- any element of the device that contacts the patient must be demonstrated to be biocompatible;
- appropriate analysis and/or testing must validate electromagnetic compatibility (EMC) and electrical safety, including the safety of any battery used in the device;
- software validation, verification, and hazard testing must be performed; and
- documented clinical experience must demonstrate safe and effective use for stimulating saliva production by addressing the risks of damage to intraoral tissue or dentition and of ineffective treatment and must capture any adverse events observed during clinical use.

Table 1 demonstrates how these special controls will mitigate each risk to health described in section IV.

Table 1.--Risks to Health and Mitigation Measures for Electrical Salivary Stimulator System

Identified Risk to Health	Mitigation Measures
Hazards caused by electrical equipment	Design characteristics EMC and electrical safety analysis and/or testing Software validation, verification, and hazard testing Documented clinical experience
Hazards caused by electromagnetic interference and electrostatic discharge	Design characteristics EMC and electrical safety analysis and/or testing
Damage to intraoral tissue or dentition	Design characteristics Documented clinical experience
Adverse tissue reaction	Biocompatibility

VII. 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.

VIII. Paperwork Reduction Act of 1995

This proposed 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 part 807, subpart E have been approved under OMB control number 0910-0120.

IX. Proposed Effective Date

FDA proposes that any final order based on this proposal become effective 30 days after the date of publication in the Federal Register.

X. Comments

Interested persons may submit either electronic comments regarding this document 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.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq., as amended) 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. Add § 872.5560 to subpart F to read as follows:

§ 872.5560 Electrical salivary stimulatory system.

(a) Identification. An electrical salivary stimulatory system is a prescription intraoral device that is intended to electrically stimulate a relative increase in saliva production.

(b) Classification. Class II (special controls). The special controls for this device are:

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

(2) Any element of the device that contacts the patient must be demonstrated to be biocompatible;

(3) Appropriate analysis and/or testing must validate electromagnetic compatibility and electrical safety, including the safety of any battery used in the device;

(4) Software validation, verification, and hazard testing must be performed; and

(5) Documented clinical experience must demonstrate safe and effective use for stimulating saliva production by addressing the risks of damage to intraoral tissue and of ineffective treatment and must capture any adverse events observed during clinical use.

Dated: September 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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