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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

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

Dental Devices; Reclassification of Electrical Salivary
Stimulator System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the salivary stimulator system, a postamendments Class III device, into class II (special controls) and to rename the device the ``electrical salivary stimulator system.'' The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective December 21, 2015.

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

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 section 513(f)(3) 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 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))).

On September 18, 2014, FDA published an order in the Federal Register to reclassify the device (79 FR 56027) (the ``proposed order''). The period for public comment on the proposed order closed on December 17, 2014. FDA received and has considered 20 comments on the proposed order, as discussed in section II.

II. Public Comments in Response to the Proposed Order

Of the 20 public comments that FDA received in response to the proposed order, 17 comments supported the proposed reclassification and 3 comments were opposed. All of the commenters were individuals, 12 of whom identified themselves as medical practitioners. Eight of these 12 practitioners claimed prior research experience with the device. Three commenters claimed experience with the device as patients in clinical trials.

All of the practitioners' and patients' comments were supportive of the reclassification proposal. All of the practitioners with prior experience administering the device noted favorable results for some of their patients and no adverse events. The other four practitioners who commented either had recommended, or if available would recommend, the device as a non-pharmaceutical option for treating dry mouth conditions.

Five commenters did not claim any prior professional or patient experience with the device. Of these comments, two favored finalization of the proposed reclassification based on the evidence presented in the proposed order.

Three comments opposed the proposed reclassification. None of these commenters claimed prior professional or patient experience with the device. One commenter believed that the proposed order adequately addressed safety concerns but failed to provide convincing evidence of the effectiveness of the device.

FDA disagrees with the comment. The special control requiring documented clinical experience will allow the Agency to require information on each device's effectiveness in actual clinical use.

Two commenters believed that the devices should undergo further clinical trials to evaluate device and human factors risks, and that electrically powered salivary stimulators are inherently hazardous and subject to misuse and, without conclusive test results, should continue to be classified as Class III devices and be subject to premarket approval.

The Agency disagrees that electrical salivary stimulator systems should

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remain class III and subject to premarket approval. The Agency believes that the special controls required in this final order provide a reasonable assurance of safety and effectiveness for these devices. FDA believes it has identified the risks to health (see section VI of the proposed order) and that the mitigation measures described in the final order will be effective in mitigating the risks described in the two comments, including the risks associated with the low-voltage electrical features of the devices. In particular, the special control requiring documented clinical experience will allow the Agency to require information on each device's safety and effectiveness in actual clinical use, including any human factors risks. These devices utilize technology similar to that used in other class II medical devices such as transcutaneous electrical nerve stimulators. The Agency believes that its experience with similar devices and the lack of adverse events for salivary stimulators in FDA's Manufacturer and User Facility Device Experience (MAUDE) database and peer-reviewed literature provide sufficient information to establish special controls that mitigated the risks to health identified for this device type in the proposed order.

The Agency is making a minor modification to the proposed special controls for electrical salivary stimulator systems by replacing the term ``geometry'' in the first special control with the term ``device design.'' FDA makes this revision to clarify the intent of the special

control.

III. The Final Order

Under section 513(f)(3) 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 salivary stimulator system devices from class III to class II, rename them electrical salivary stimulator systems, and establish special controls by revising part 872 (21 CFR part 872).

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 electrical salivary stimulator systems, and therefore, this device type is not exempt from premarket notification requirements.

The device is assigned the generic name electrical salivary stimulator system, and it is identified as a prescription intraoral device intended to electrically stimulate a relative increase in saliva production. FDA is identifying the device under this new name to distinguish it from other devices that stimulate saliva flow via non-electrical means.

Under this final order, the electrical salivary stimulatory system device is 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 (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 Sec. 801.109.

Under section 513(f)(3) of the FD&C Act, FDA is adopting its findings as published in the preamble to the proposed order, with the following correction: FDA stated in the proposed order that the Agency utilized section 520(h)(4) of the FD&C Act to review data contained in premarket approval applications (PMAs) approved 6 or more years before the date of the proposed order. The Agency would like to clarify that this language was included unintentionally, and that the provisions of section 520(h)(4) were not utilized in this rulemaking proceeding.

IV. Environmental Impact, No Significant Impact

We have 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.

V. Paperwork Reduction Act of 1995

This final administrative 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, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

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, 21 CFR part 872 is amended as follows:

PART 872--DENTAL DEVICES

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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.

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2. Add Sec. 872.5560 to subpart F to read as follows:

Sec. 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 device design, 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: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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