DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA–2015–N–4328]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Tympanic Membrane Contact Hearing Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the tympanic membrane contact hearing aid into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the tympanic membrane contact hearing aid's classification. 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 January 21, 2016. The classification was applicable on September 29, 2015.

FOR FURTHER INFORMATION CONTACT: Cherish Giusto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2432, Silver Spring, MD 20993–0002, 301–796–9679, *cherish.giusto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), 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) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On January 5, 2015, EarLens Corporation submitted a request for classification of the EarLens™ Contact Hearing Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on September 29, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.3315.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a tympanic membrane contact hearing aid will need to comply with the special controls named in this final administrative order.

The device is assigned the generic name tympanic membrane contact hearing aid, and it is identified as a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks:

TABLE 1—TYMPANIC MEMBRANE CONTACT HEARING AID RISKS AND MITIGATION MEASURES

Identified risks	Mitigation methods
Adverse Tissue Reactions	Biocompatibility.
	Labeling.
Electromagnetic Incompatibility	Non-Clinical Performance Testing.
	Labeling.
MRI Incompatibility	Labeling.
Overheating of Ear Canal or Skin	Non-Clinical Performance Testing.
	Clinical Performance Testing.

TABLE 1—TYMPANIC MEMBRANE CONTACT HEARING AID RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation methods
	Labeling.
Damage to Eyes from Direct Laser Exposure [1]	Labeling.
Trauma/Damage to the Ear Canal, Tympanic Membrane, or Middle Ear System	Non-Clinical Performance Testing.
	Clinical Performance Testing.
	Training.
	Labeling.
Residual Hearing Loss	Non-Clinical Performance Testing.
	Clinical Performance Testing.
	Labeling.
Ear Infections	Clinical Performance Testing.
	Labeling.
Vertigo or Tinnitus	Clinical Performance Testing.
	Labeling.
Dampening of Residual Hearing When the Device is Turned Off	Clinical Performance Testing.
	Labeling.

[1] A tympanic membrane contact hearing aid may contain a Class 1 laser product in its removable external component, which users will remove from their ear when the device is not in use (for example, to sleep or bathe). When being handled off of the ear, it is possible that the user could look directly at the laser. Thus, there is a risk of ''damage to eyes from direct laser exposure.'' As mitigation, the user should be warned in labeling not to look directly into the laser or aim it at their eyes.

FDA believes that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Tympanic membrane contact hearing aids are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (*Prescription devices*).

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), 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 to FDA a premarket notification, prior to marketing the device, which contains information about the tympanic membrane contact hearing aid they intend to market.

II. 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.

III. 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.

IV. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *http://www.regulations.gov*. FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. DEN150002: De novo Request per 513(f)(2) from EarLens Corporation, dated January 5, 2015.

List of Subjects in 21 CFR Part 874

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 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 874.3315 to subpart D to read as follows:

§ 874.3315 Tympanic membrane contact hearing aid.

(a) *Identification.* A tympanic membrane contact hearing aid is a prescription device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.

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

(1) The patient contacting components must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, and must include:

(i) Mechanical integrity testing;

(ii) Electrical and thermal safety testing;

(iii) Software verification, validation, and hazard analysis;

(iv) Reliability testing consistent with expected device life;

(v) Electromagnetic compatibility testing; and

(vi) Validation testing of device output and mechanical force applied to the tympanic membrane in a clinically appropriate model.

(3) Clinical performance testing must characterize any adverse events observed during clinical use, and

demonstrate that the device performs as intended under anticipated conditions of use.

(4) Professional training must include the ear impression procedure, correct placement, fitting, monitoring, care, and maintenance of the device.

(5) Labeling must include the following:

(i) A detailed summary of the adverse events and effectiveness outcomes from the clinical performance testing;

(ii) Detailed instructions on how to fit the device to the patient;

(iii) Instructions for periodic cleaning of any reusable components;

(iv) Information related to electromagnetic compatibility; and

(v) Patient labeling that includes:

(A) A patient card that identifies if a patient has been fitted with any non-self- removable components of the device and provides relevant information in cases of emergency;

(B) Information on how to correctly use and maintain the device;

(C) The potential risks and benefits associated with the use of the device; and

(D) Alternative treatments.

Dated: January 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB–2015–0004; T.D. TTB–132; Ref: Notice No. 148]

RIN 1513–AC11

Establishment of the Los Olivos District Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the approximately 22,820-acre ''Los Olivos District'' viticultural area in Santa Barbara County, California. The viticultural area is located within the Santa Ynez Valley viticultural area and the larger, multicounty Central Coast viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: This final rule is effective February 22, 2016.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Department Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these provisions.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Los Olivos District Petition

TTB received a petition from C. Frederic Brander, owner and winemaker of the Brander Vineyard, proposing the establishment of the ''Los Olivos District'' AVA in Santa Barbara County, California. There are 12 bonded wineries and approximately 47 commercially producing vineyards covering a total of 1,120 acres within the proposed AVA. The proposed Los Olivos District AVA shares its western boundary with the eastern boundary of the Ballard Canyon AVA (27 CFR 9.230) and its eastern boundary with the western boundary of the Happy Canyon of Santa Barbara AVA (27 CR 9.217), but it does not overlap either of these AVAs. It is located within the Santa Ynez Valley viticultural area and the larger, multicounty Central Coast viticultural area.

According to the petition, the distinguishing features of the proposed Los Olivos District AVA include its topography, soils, and climate. The proposed AVA is located on a broad alluvial terrace plain of the Santa Ynez