4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. FDA-2019-N-4328]

Medical Devices; Ear, Nose, and Throat Devices; Classification of the Self-Fitting Air-Conduction Hearing Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the self-fitting air-conduction hearing aid into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the self-fitting air-conduction hearing aid's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The classification was applicable on October 5, 2018.

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

Upon request, FDA has classified the self-fitting air-conduction hearing aid as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section

207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a

substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On May 11, 2018, Bose Corp. submitted a request for De Novo classification of the Bose Hearing Aid. 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.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on October 5, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 874.3325. We have named the generic type of device self-fitting air-conduction hearing aid, and it is identified as a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

Table 1.--Self-Fitting Air-Conduction Hearing Aid Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Diminished hearing due to over-amplification caused by: • Excessively high sound output levels in the ear canal • Device malfunction • Interference with or from other devices	Software verification, validation, and hazard analysis; Electroacoustic performance testing; and Electromagnetic compatibility (EMC) testing
Listening fatigue or failure to provide sound awareness due to over- or under-amplification caused by: • Poor fitting • Device malfunction • Use error • Interference with or from other devices	Clinical data; Usability testing; Software verification, validation, and hazard analysis; Electroacoustic performance testing; EMC testing; and Labeling
Tissue heating due to exposure to non-ionizing radiation emitted by wireless technology	Wireless technology evaluation; and Labeling
Tissue trauma/damage in the ear canal or other patient contacting areas due to: • Excessively long ear piece • Device malfunction • Use error	Usability testing; Electrical and thermal safety testing; and Labeling
Missed or delayed medical diagnosis or treatment due to failure to self-identify correct population and condition	Labeling

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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 the guidance document "De Novo Classification Process (Evaluation of Automatic Class III Designation)" have been approved under OMB control number 0910-0844; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910-0231; 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 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 part 874 continues to read as follows:

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

2. Add § 874.3325 to subpart D to read as follows:

§ 874.3325 Self-fitting air-conduction hearing aid.

(a) *Identification*. A self-fitting air-conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings.

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

(1) Clinical data must evaluate the effectiveness of the self-fitting strategy.

(2) Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested.

(3) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device.

(4) Software verification, validation, and hazard analysis must be performed.

(5) If the device incorporates wireless technology:

(i) Performance testing must validate safety of exposure to non-ionizing radiation;

(ii) Performance data must validate wireless technology functions; and

(iii) Labeling must specify instructions, warnings, and information relating to wireless technology and human exposure to non-ionizing radiation.

(6) Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.

(7) Patient labeling must include the following:

(i) Information on how a patient can self-identify as a candidate for the device;

(ii) Information about when to seek professional help;

(iii) A warning about using hearing protection in loud environments;

(iv) A warning about staying alert to sounds around the user of the device;

(v) Technical information about the device, including information about EMC; and

(vi) Information on how to correctly use and maintain the device.

Dated: October 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-23464 Filed: 10/25/2019 8:45 am; Publication Date: 10/28/2019]