



August 19, 2019

Bose Corporation
% Deborah Arthur
Regulatory Consultant to Bose Corporation
DArthurConsulting
231 Queens Rd.
Charlotte, North Carolina 28204

Re: DEN180026
Trade/Device Name: Bose Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QDD
Dated: May 7, 2018
Received: May 11, 2018

Dear Deborah Arthur:

This letter corrects our classification order dated October 5, 2018.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Bose Hearing Aid with the following indications for use:

The Bose Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Bose Hearing Aid, and substantially equivalent devices of this generic type, into Class II under the generic name self-fitting air-conduction hearing aid.

FDA identifies this generic type of device as:

Self-fitting air-conduction hearing aid. 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.

The Bose Hearing Aid is subject to labeling and conditions for sale requirements under 21 CFR 801.420 and 801.421.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On May 11, 2018, FDA received your De Novo requesting classification of the Bose Hearing Aid. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Bose Hearing Aid into class I or II, it is necessary that the proposed class have sufficient regulatory 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 De Novo request, FDA has determined that, for the previously stated indications for use, the Bose Hearing Aid can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Diminished hearing due to over-amplification caused by: <ul style="list-style-type: none"> • 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 Electromagnetic compatibility (EMC) testing
Listening fatigue or failure to provide sound awareness due to over- or under-amplification caused by: <ul style="list-style-type: none"> • 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 Electromagnetic compatibility (EMC) testing Labeling
Tissue heating due to exposure to non-ionizing radiation emitted by wireless technology	Wireless technology evaluation Labeling

Tissue trauma/damage in the ear canal or other patient contacting areas due to: <ul style="list-style-type: none"> • Excessively long ear piece • Device malfunction • Use error 	Usability testing Electrical and thermal safety testing Labeling
Missed or delayed medical diagnosis or treatment due to failure to self-identify correct population and condition	Labeling

In combination with the general controls of the FD&C Act, the self-fitting air-conduction hearing aid is subject to the following special controls:

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:
 - (A) Performance testing must validate safety of exposure to non-ionizing radiation;
 - (B) Performance data must validate wireless technology functions; and
 - (C) 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:
 - (A) Information on how a patient can self-identify as a candidate for the device;
 - (B) Information about when to seek professional help;
 - (C) A warning about using hearing protection in loud environments;
 - (D) A warning about staying alert to sounds around the user of the device;
 - (E) Technical information about the device, including information about electromagnetic compatibility; and
 - (F) Information on how to correctly use and maintain the device.

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 type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the self-fitting hearing aid they intend to market prior to marketing the device.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of this letter, please contact Cherish Giusto at 301-796-9679.

Sincerely,

Angela C. Krueger
Associate Director, Regulation, Policy and Guidance
Office of Product Evaluation and Quality
Center for Devices and Radiological Health