June 3, 2021

Bose Corporation
Bryn Kieras
Regulatory Affairs Program Manager
The Mountain
Framingham, Massachusetts 01701

Re: K211008
Trade/Device Name: Bose SoundControl Hearing Aids
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QDD

Dear Bryn Kieras:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 5, 2021. Specifically, FDA is updating this SE Letter to correct the Indications For Use (IFU) form Type of Use from Over-The-Counter Use (21 CFR 801 Subpart C) to Restricted Device (per 21 CFR 801.420 and 21 CFR 801.421).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, Ph.D. OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, (301) 796-6481, shu-chen.peng@fda.hhs.gov.

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

May 5, 2021

Bose Corporation
Bryn Kieras
Regulatory Affairs Program Manager
The Mountain
Framingham, Massachusetts 01701

Re: K211008
Trade/Device Name: Bose SoundControl Hearing Aids
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QDD
Dated: April 1, 2021
Received: April 5, 2021

Dear Bryn Kieras:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211008

Device Name
Bose SoundControl™ Hearing Aid

Indications for Use *(Describe)*
The Bose SoundControl™ Hearing Aids 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.

Restricted Device (per 21 CFR 801.420 and 21 CFR 801.421).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY - K211008

Applicant: Bose Corporation

Address

The Mountain Rd

Framingham, MA 01701

Contact: Bryn Kieras

Phone: (978) 457-2972

Fax: N/A

Establishment Registration Number: 3003361262

Trade Name: Bose SoundControl Hearing Aids

Common/Usual Name: Self-Fit Wireless Air-Conduction Hearing Aid

Classification Name: Self-Fit Wireless Air-Conduction Hearing Aid

Regulation Number: 874.3325

Product Code: QDD

Classification: Class II

Panel: Ear, Nose, and Throat Devices

Predicate Device: Bose Hearing Aid (DEN180026)

Submitter/510(k) Holder: Bose Corporation

Submission Date: April 1, 2021

Device Description:

Per 21 CFR 874.3325 a self-fitting wireless 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. Self-fitting wireless air conduction hearing aids are class II medical devices.

The Bose SoundControl Hearing Aids (Model BMD0012) are self-fitting wireless air conduction hearing aids consisting of the Novidan Inc. hardware, Bose software, the Bose Hear app, and accessories supplied in the carton.

Each hearing aid in the pair functions and interacts with the Bose Hear app independently and as a system. The hearing aids are powered by a disposable size 312 zinc-air battery. The hearing aids incorporate microphones for audio input and sound is delivered to the ear via a receiver that can be coupled with open or closed domes. The hearing aids are controlled via on-board button controls and wirelessly via the Bose Hear app (iOS and Android). The controls allow the user to configure parameters, settings, and listening modes.

Intended Use:

Bose SoundControl Hearing Aids are a pair of user-fitted wireless air conduction hearing aids intended for use by individuals 18 years and older with perceived mild to moderate hearing impairment.

Indications for Use:

The Bose SoundControl™ Hearing Aids are 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.

Self-Selection Labeling:

Self-Selection Labeling had been included in the Bose SoundControl Hearing Aids IFU to mitigate the risk of improper self-selection. Summarized, it addresses:

- Identifying situations in which Bose SoundControl Hearing Aids may help you hear better.
- Identifying situations in which Bose SoundControl Hearing Aids may not be right for the user.
- Identifying criteria that indicate the user should see a hearing professional.
- Informing the user that the Bose SoundControl Hearing Aids will not restore normal hearing
- Informing the user that it is good health practice to have hearing loss evaluated by an appropriate healthcare professional.

Special Controls:

The Bose SoundControl Hearing aid conforms to the special controls stated in 21 CFR 874.3325. Bose satisfied these requirements through:

- Clinical Data

- Non-Clinical Performance Testing
- Human Factors Validation
- Labeling

Comparison of Technological Characteristics:

Both the subject (Bose SoundControl Hearing Aids) and the predicate (Bose Hearing Aid) are self-fit direct-to-consumer hearing aids indicated for individuals 18 and older with perceived mild to moderate hearing impairment. The same fundamental technology is present in both hearing aids to allow the user to control and customize the device to the user's hearing needs.

Both devices contain the same technological characteristics:

- Self-Fit Hearing Aid
- Home Healthcare Environment use
- Bluetooth
- On Device Controls
- App (Bose Hear app)
- Software Platform Compatibility (iOS, Android)

Technological differences of the Bose SoundControl Hearing Aids were as follows:

- An updated Form Factor to a traditional RIC style hearing aid
- A Replaceable Battery
- Removal of Telephony and Streaming
- Removal of Active Noise Reduction (ANR)

The Bose SoundControl Hearing Aids were evaluated through Clinical and Non-Clinical Performance Testing to demonstrate the substantial equivalence to the predicate device as described in DEN180026.

Clinical Data:

The results of the clinical study used in DEN180026 provide conclusive evidence that the Bose Self-Fitting method results in outcomes not in any way inferior to professional fitting for adults with mild to moderate hearing loss. Based on patient satisfaction and preference reports, subjects in the Self-Fit Group were satisfied with and preferred their own self-adjusted settings to the professionally-selected settings.

A clinical validation study demonstrated that Bose SoundControl Hearing Aids deliver adequate amplification to compensate for mild to moderate hearing loss (Figure 1).

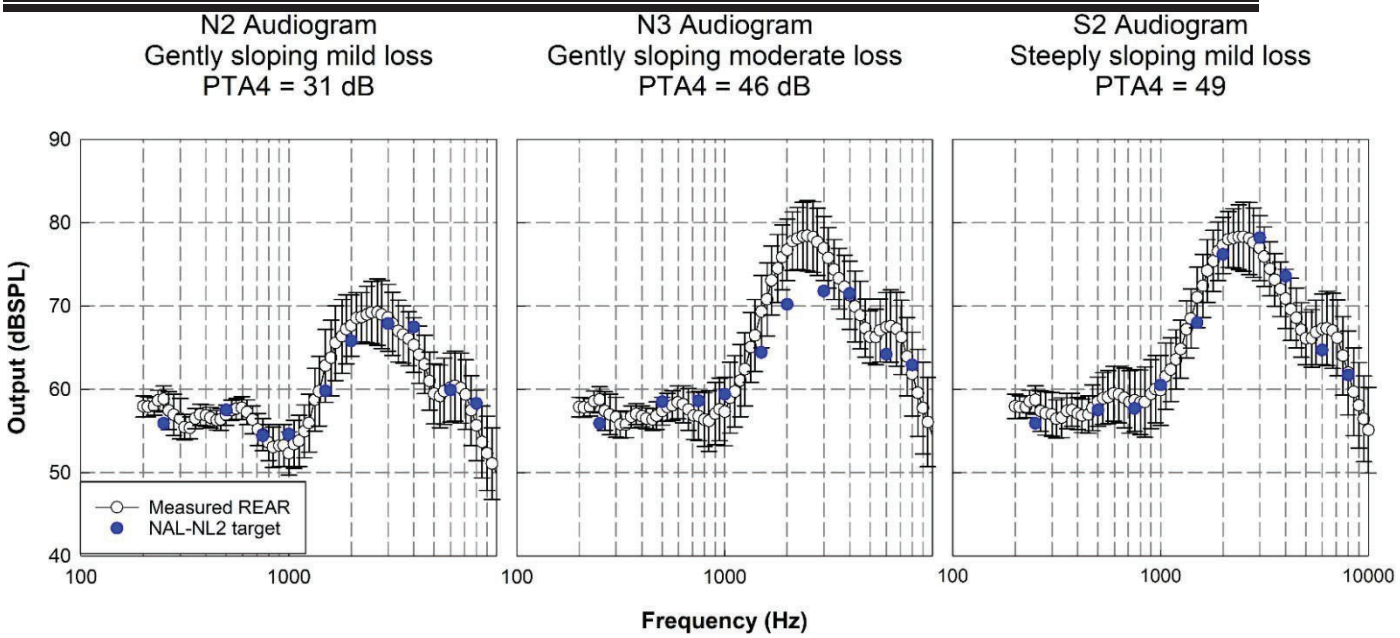

Figure 1: *Mean (open black symbols) ± 1 standard deviation (error bars) of the real-ear aided response (REAR) measured when matching to NAL-NL2 amplification targets (filled blue symbols) for average conversational speech. REAR was obtained in 34 ears, with open and closed eartips, for three standard audiometric configurations (N2, N3 and S2; Bisgaard et al, 2010) representing mild to moderate hearing loss.*

Because the self-fitting method in the Bose SoundControl is the same as the one used in the DEN180026 device the prior DEN180026 clinical data can be used to show that the Bose SoundControl also results in outcomes not in any way inferior to professional fitting for adults with mild to moderate hearing loss.

Non-clinical Performance Testing:

Bose conducted performance testing on the Bose SoundControl Hearing Aids to provide a reasonable assurance of safety and effectiveness of the device as compared to the Bose Hearing Aid (DEN180026). The results are summarized in the table below:

Test Standard/ Method	Test Purpose/ Description	Result
IEC 60601- 1:2005+A1:2012 **IEC 60601-2-66:2019** **IEC 60601-1-11:2015***	Electrical Safety	Pass
IEC 60601-1-2:2014	Electromagnetic Compatibility (EMC)	Pass
ANSI/ASA S3.22 2014	Electroacoustic	Pass
Bose-specified procedure, 'Medical – Usability Engineering Procedure' specifies how to apply human factors engineering methods to product development **IEC 60601-1-6: 2010+A1:2013**	Usability Engineering	Pass

Test Standard/ Method	Test Purpose/ Description	Result
10993-1:2009/TC 1 2010 Assessment ISO 10993-5 Cytotoxicity ISO 10993-10 Irritation / Sensitization	Biocompatibility	Pass
IEC 62304:2006+A1:2015	Software	Pass

*Applicable sections

The range of testing and all acceptance criteria are appropriate to evaluate this device based on its proposed intended use. All acceptance criteria were met.

ANSI/ASA S3.22 2014 Measurements

In order to prove substantial equivalence with the predicate device, Bose evaluated the ANSI S3.22 data set from the predicate (DEN180026) devices ANSI/ASA S3.22 measurements in order to establish substantial equivalence in acoustic performance.

Test	Bose Hearing Aid (DEN180026)	Bose SoundControl Hearing Aids	Discussion
OSPL90 curve	Figure 2 (left)	Figure 3 (left)	
Max OSPL90	115 dBSPL	113 dBSPL	Same
HFA OSPL90	112 dBSPL	106 dBSPL	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
HFA FOG	43 dB	30 dB	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
RTG	36 dB	29 dB	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
Frequency response	Figure 2 (right)	Figure 3 (right)	
Frequency range	<200 - >8000 Hz	<200-8000 Hz	Same
Harmonic Distortion	3.6%	<1%	Same
EIN	26 dBSPL	<27 dBSPL	Same
Battery current	N/A	2.8 mA	Predicate device was rechargeable

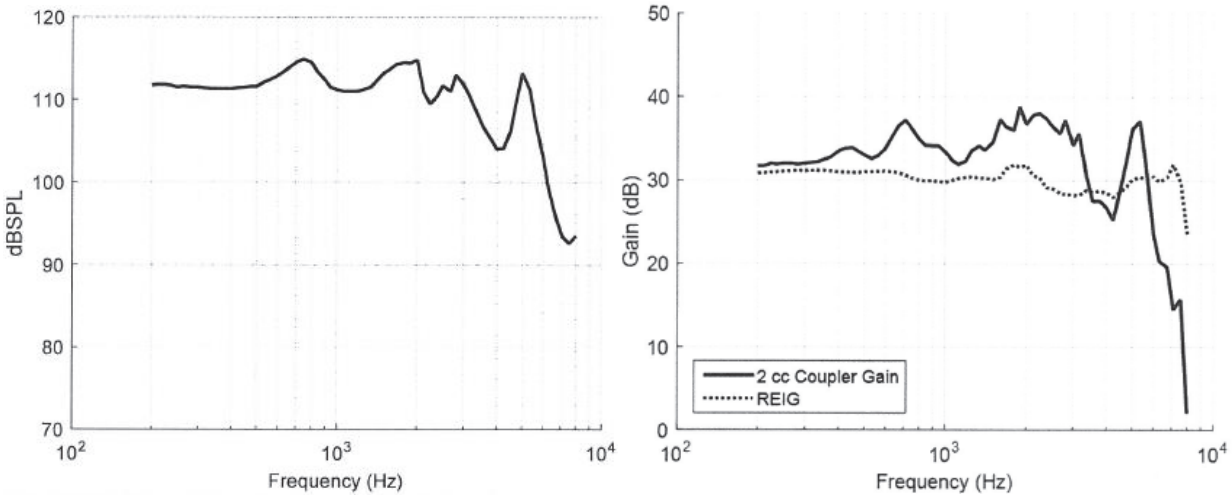

Figure 2: *OSPL90 (left panel) and frequency response (right panel, solid line) curves for Bose Hearing Aid as measured in 2cc coupler. Note that these curves represent a single measurement of one unit.*

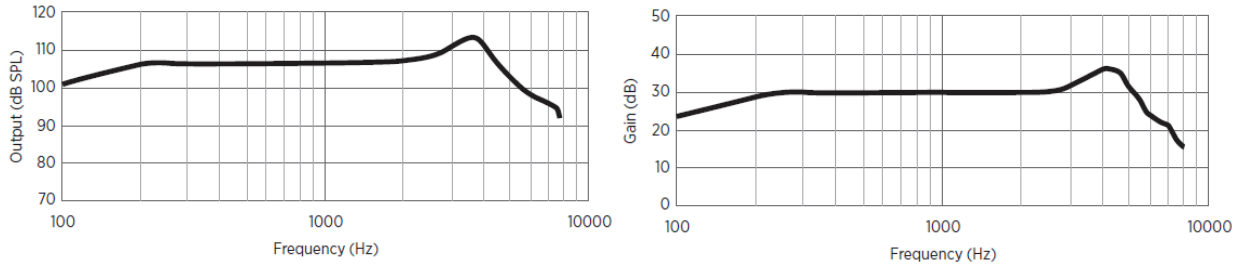

Figure 3: *Nominal OSPL90 (left panel) and frequency response (right panel) curves for Bose SoundControl Hearing Aids as measured in 2cc coupler.*

Based on the above information, Bose concludes that the Bose SoundControl Hearing Aids are substantially equivalent to the predicate device Bose Hearing Aid (DEN180026).

Usability Testing

Bose conducted a human factors validation test (i.e., summative usability test) of the Bose SoundControl Hearing Aids in accordance with FDA's final guidance, Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff (2016). The human factors validation test included 20 untrained participants representing the intended user population (individuals 18 year of age or older with perceived mild to moderate hearing impairment), each of whom performed hands-on use scenarios and knowledge tasks with the Bose SoundControl Hearing Aids, including the Bose Hear app, accessories, and user documentation. After the use scenarios and knowledge tasks, the moderator asked open-ended questions to collect participants' subjective assessments of use safety and usability. The test found that the Bose SoundControl Hearing Aids are safe and effective for the intended users, uses, and use environments.

Substantial Equivalence:

The Bose SoundControl Hearing Aids has the same intended use and fundamental technology as the predicate, the Bose Hearing Aid (DEN180026). In the same manner as its predicate the Bose SoundControl Hearing Aids are a user-fitted wireless air-conduction hearing aid intended for over-the-counter use by individuals 18 years or older with perceived mild to moderate hearing impairment. The change discussed in the submission is about the Bose SoundControl Hearing Aids new form factor. The wearable portion of the device is a familiar RIC design powered by disposable size 312 zinc-air battery. Clinical data proves that the Bose SoundControls Hearing Aids are substantially equivalent to its predicate device in acoustic performance. Non-clinical performance testing has been derived from and conducted to ensure that device form factor change does not impact the basic threshold for safety and effectiveness as established by the predicate DEN180026. Device firmware is derived from the DEN180026 device with minor modifications related to the electronics and smaller footprint. Software is derived from the DEN180026 with minor modifications to the user interface for aesthetic reasons. There has been no change from the Self-Fit technology demonstrated in the predicate device submission. Design verification results demonstrate that the subject device (inclusive of software modifications) has substantially equivalent performance to the predicate.

Conclusion:

The Bose SoundControl Hearing Aids are substantially equivalent in intended use and fundamental scientific technology to the Bose Hearing Aid (DEN180026). The Bose SoundControl Hearing Aids are considered as safe and effective as the predicate device for its intended use when used in accordance with its Instructions for Use.