

**DE NOVO CLASSIFICATION REQUEST FOR
BOSE® HEARING AID**

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 874.3325

CLASSIFICATION: Class II

PRODUCT CODE: QDD

BACKGROUND

DEVICE NAME: Bose® Hearing Aid

SUBMISSION NUMBER: DEN180026

DATE OF DE NOVO: May 11, 2018

CONTACT: Bose Corporation
The Mountain
Framingham, MA 01701

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.

LIMITATIONS

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

Limitations on device use are included in the Instructions for Use as "Important Information" and "Warnings, Precautions, and Safety Considerations."

Important Information from the Instructions for Use:

This product may help you hear better if you:

- strain to follow conversations when others don't, especially in noisy places.
- have trouble understanding the TV or telephone calls.

This product may not be right for you if you:

- Consistently experience feedback (whistling) of the earbuds when you turn up World Volume to a level that is comfortable for you, even after you have followed the suggestions in the Instructions for Use to make sure your eartips fit properly.
- Feel the hearing aid is not providing enough amplification even at the highest World Volume setting.

A hearing health care professional may be able to help you select a different hearing aid solution to meet your needs.

You should see a hearing health care professional if you:

- Have a visible deformity of the ear.
- Have a current ear infection or a history of active discharge from one or both ears within the past 90 days.
- Have sudden or rapid progression of hearing loss within the past 90 days in one or both ears.
- Have acute or chronic dizziness, poor dexterity, poor vision, or significant dementia.
- Suspect that you have significant ear wax accumulation or a foreign object in the ear canal. Symptoms of significant ear wax accumulation can include itching in your ear, a feeling of fullness in your ear, and/or reduced hearing.
- Experience pain or discomfort in the ear.
- Have a noticeable difference in hearing between ears.
- Have sudden onset or rapid worsening of tinnitus (ringing in the ear) in one or both ears within the past 90 days.

It is good health practice for a person with a hearing loss to have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear). Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS AND PRECAUTIONS.

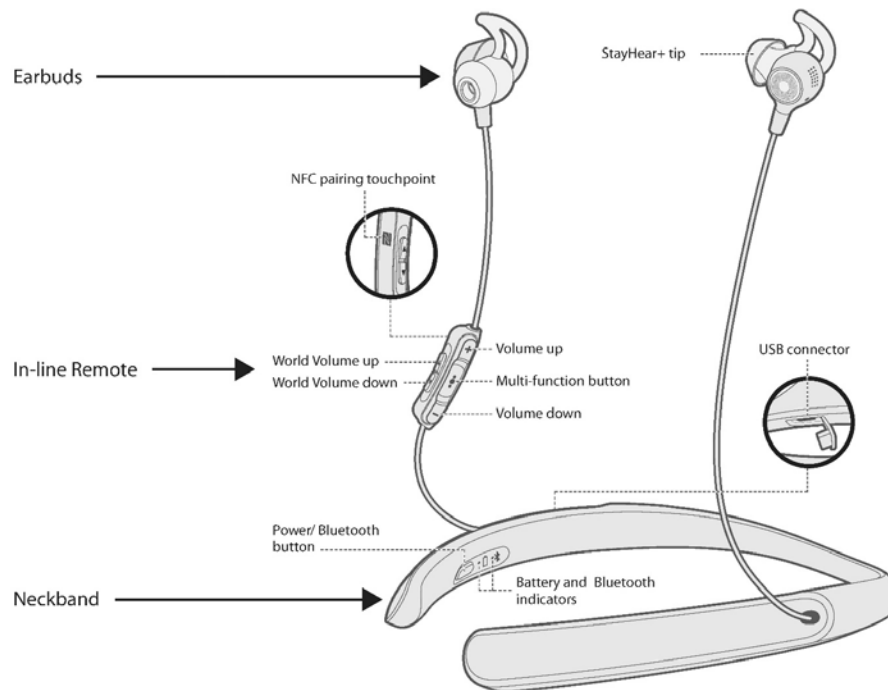
DEVICE DESCRIPTION

The Bose® Hearing Aid is a user-fitted wireless air-conduction hearing aid intended for use by individuals 18 years of age and older with perceived hearing impairment. It incorporates microphones on the earbuds for audio input into the ear, and it can be controlled wirelessly via Bluetooth® using a handheld device (iOS or Android) through the Bose Hear mobile app. There is an on-device user control (in-line remote) on the right cable (attached to neckband) that allows separate control of hearing aid (“world”) volume and streaming audio volume, as well as control of directional hearing aid mode. In addition to hearing aid functionality for environmental listening, the Bose Hearing Aid can be used for placing and receiving telephone calls and for streaming audio from a Bluetooth compliant mobile device that has been paired with the Bose Hearing Aid. The controls accessible through the Bose Hear mobile application and on the hearing aid are used by the user to configure parameters, settings, and listening modes.

Hearing Aid System Components

The Bose Hearing Aid (**Figure 1**) consists of a flexible neckband housing a rechargeable lithium ion battery and electronic components with extending cables for the right and left ears. The system also includes a 5 Volt USB AC to DC Power supply wall charger with an attaching USB cable (not shown).

Figure 1. Bose Hearing Aid System



Earbuds are connected to the neckband by flexible wires and on each earbud is mounted a Bose StayHear+ eartip; three sizes of tips are packaged with the product so that the user can choose the optimal size.

The Bose Hearing Aid is self-fitted by the user by adjustment of the level (World Volume) and spectral tilt (Treble/Bass) settings. The hearing aid has four (two per earbud) microphones that may be configured in omnidirectional or directional modes during use. The Bose Hear mobile application gives the wearer access to all gain settings (e.g. World Volume and Treble/Bass) and device configurations while the in-line remote buttons (**Figure 1**) can be used to adjust the World Volume and directional mode.

These settings are preserved between use sessions and the settings from the previous use session are recalled upon power up of the device. The Bose Hearing Aid has Active Noise Reduction (ANR), which is established using feedback and feedforward control loops to reduce environmental sounds. The Bose Hearing Aid is powered by a rechargeable 3.7 V, 250 mAh Li-ion battery pack and is recharged using a 5 Volt USB AC to DC power supply wall charger provided with the hearing aid.

Hearing Aid Features

Hearing aid signal processing includes 12-channel wide dynamic range compression amplification with compression threshold fixed at speech-equivalent 52 decibels (dB) sound pressure level (SPL). The Bose Hearing Aid includes Active Noise Reduction (ANR) to reduce environmental noise and to decrease amplification of the user's own voice typical of an occluding earbud. ANR is continuously active, even when the Bose Hearing Aid is used as a hearing aid.

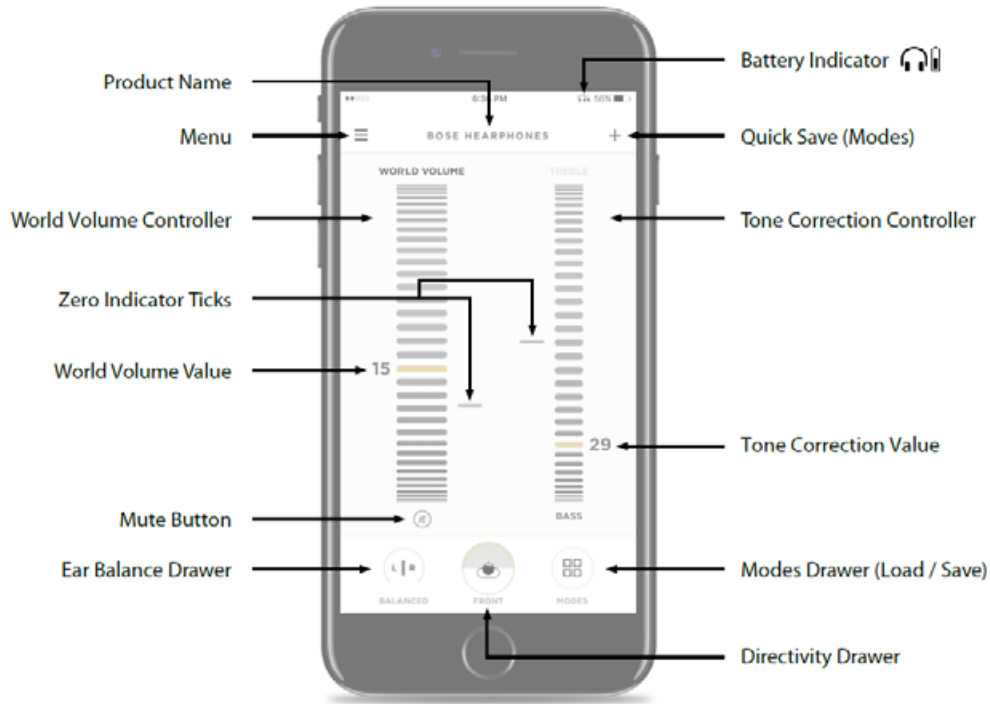
Additional features include:

- Feedback cancellation
- Steady state noise reduction
- Directionality (three modes controllable by user)
- Impulse noise control
- Left/Right balance
- Bluetooth compliant 2.4 GHz wireless radio for streaming audio, telephony, and control
- Microphone array for telephony
- Volume-optimized audio equalization (selectable high-frequency boost when listening to streamed content)
- Voice prompts
- Battery life of approximately 10 hours
- NFC pairing for compatible Android devices

Hearing Aid User Interface

The Bose Hear mobile application is designed to function with a user's compatible personal smartphone or tablet device. It is available free for download on iOS or Android based systems. The Bose Hear mobile application (Bose Hear App) is used to set gain parameters as well as device settings on the Bose Hearing Aid.

Figure 2. Bose Hear Mobile App home screen



- **MODES**

Allows the user to save and name settings that he/she has identified for different use cases or use environments (**Figure 2**).

- **WORLD VOLUME CONTROL WHEEL**

Controls gain and compression parameters in 12 channels of wide dynamic range compressive hearing aid signal processing. As the user adjusts from zero to top of control, positions correspond to prescriptive fittings for hearing losses up to moderate hearing loss. The user can manipulate the wheel to arrive at the optimal setting for his/her hearing status, which will be the one that provides greatest perceived benefit and comfort.

- **TONE CORRECTION CONTROL WHEEL**

Controls spectrum balance. This is used to balance low and high frequency sound to suit the user's sound quality preferences.

- **EAR BALANCE**

Allows user to balance volume across ears (**Figure 3a**).

- **DIRECTIVITY**

Allows user to select from three modes that provide three levels of focus on sounds in front of the user: no emphasis (Everywhere), moderate emphasis (Front), and maximum emphasis (Focused). When attempting to converse with a person in front of the user in a noisy

environment, the user will experience maximum benefit when directional control is set to maximum emphasis (**Figure 3b**).

Figure 3a. Balance Screen

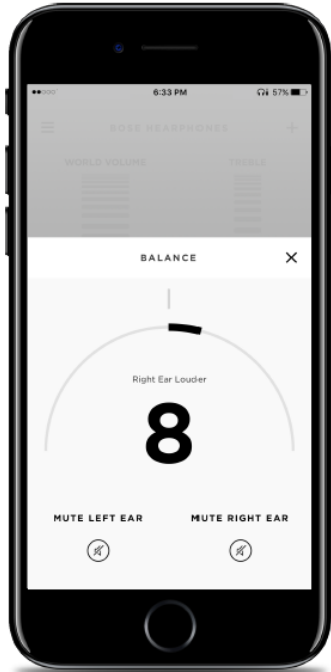
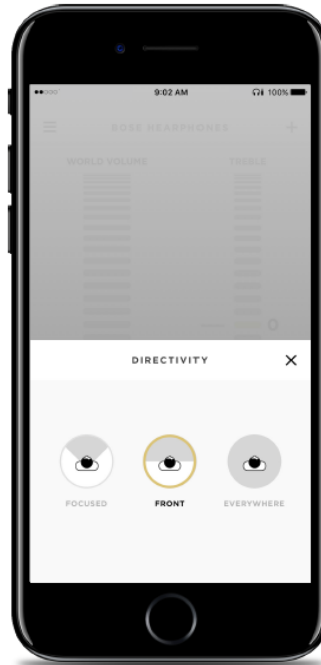


Figure 3b. Directivity Screen



A subset of Bose Hearing Aid functions can be controlled by buttons on the device. The buttons in-line with the right cable control the following functions:

- World Volume up & down
- Change directivity modes (by simultaneously pressing both World Volume buttons)
- Streamed volume up & down
- Control of telephone and streamed sources

The power/pairing button is located on the underside of the neckband, and performs the following functions:

- Power on
- Power off
- Initiate Bluetooth pairing
- Clear the Bluetooth pairing list
- Announce connection state while on

Two LED indicator lights on the inside of the neckband provide visual status of the Bluetooth connection and battery status. Optional voice prompts also provide redundant audio feedback through the earbuds related to pairing and battery status.

SUMMARY OF NONCLINICAL/BENCH STUDIES

Non-clinical/bench studies conducted on the Bose Hearing Aid to demonstrate a reasonable assurance of safety and effectiveness of the device are summarized in the following table and sections below.

Table 1. Bose Hearing Aid Test Summary Table

Test Standard/ Method	Test Purpose/ Description	Components Tested	Acceptance Criteria	Results
<ul style="list-style-type: none"> • Overvoltage Protection Circuit • Near field Communication • Battery life assessment per ANSI/CTA 2051 	Electrical Testing	Bose Hearing Aid, StayHear + medium size tip + USB Power Supply	See below	Passed
<ul style="list-style-type: none"> • IEC 60601-1:2005+A1:2012 • IEC 60601-2-66:2015 • IEC 62133:2012, Ed. 2. 	Electrical and Battery Safety	“	As defined in the listed standards (details below)	Passed
<ul style="list-style-type: none"> • IEC 60601-1-2:2014 	Electromagnetic Compatibility (EMC)	“	As defined in the listed standard	Passed
<ul style="list-style-type: none"> • AAMI TIR 69: 2017 	Wireless coexistence risk assessment	“	As defined in the listed standard	Reported
<ul style="list-style-type: none"> • Eartip fit analysis • Neckband fit verification 	Mechanical	“	See below	Accepted / Passed
<ul style="list-style-type: none"> • ANSI/CTA 2051 • ANSI/ASA S3.22 	Electroacoustic	“	Various requirement as defined in the listed standards (details below)	Passed or Reported
<ul style="list-style-type: none"> • Bose-specified procedure, ‘Medical – Usability Engineering Procedure’ specifies requirements to analyze, design, verify and validate usability • IEC 60601-1-6: 2010+A1:2013 	Usability Engineering	“	Per the requirement of the listed protocol and standard	Passed
<ul style="list-style-type: none"> • 10993-1:2009/TC 1 2010 Assessment • Cytotoxicity, Irritation, Skin Sensitization tests (standards/details below) 	Biocompatibility	Bose Hearing Aid, StayHear + medium size tip	Per the requirement of the referenced standard (details below)	Passed
<ul style="list-style-type: none"> • IEC 62304:2006+A1:2015 	Software	Bose Hearing Aid, StayHear + medium size tip + USB Power Supply + Mobile Apps (iOS and Android)	As defined in the listed standard	Passed

ELECTRICAL AND BATTERY SAFETY, ELECTROMAGNETIC COMPATIBILITY & WIRELESS COEXISTENCE/SAFETY

Verification for electrical overvoltage protection circuit verification and wireless technology is summarized in the following table:

Table 2. Electrical Testing and Wireless Technology Evaluation

Test Standard/ Method	Test Purpose/ Description	Component (s) Tested	Acceptance Criteria	Results
Overvoltage Protection Circuit Verification	To demonstrate that Bose Hearing Aid device charging subsystem is protected from application of excessive input voltage.	Bose Hearing Aid, StayHear+ medium size tip + USB Power Supply	<ul style="list-style-type: none"> • Within the permissible operating voltage range the device shall draw $127 \text{ mA} \pm 20 \text{ mA}$ of current, which indicates proper charging of the rechargeable battery. • Device shall continue to charge down to 4.4 V. • Device shall continue to charge up to at least 6.8 V and no higher than 8.45 V. • Beyond the upper limit for the operating voltage range the device shall draw no more than 2.5 mA from the power supply, indicating proper function of the protection circuitry. 	Pass
Wireless Technology Verification	To demonstrate that Bose Hearing Aid device initiates Bluetooth pairing, and Bluetooth control and streaming functionality.	Bose Hearing Aid, StayHear + medium size tip + USB Power Supply	<ul style="list-style-type: none"> • Pairing, control, streaming verification with the paired mobile device. 	Pass

In addition, as summarized above, electrical safety, battery safety, and electromagnetic compatibility (EMC) testing was conducted on the Bose Hearing Aid to verify that the device meets the requirements for basic safety and essential performance per the following international standards:

- IEC 60601-1:2005 (Ed. 3) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint). *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Edition 3.1*
- IEC 60601-2-66:2015. *Medical electrical equipment: Practical requirements for basic safety and essential performance of Hearing Instruments and Hearing Instrument Systems*
- IEC 62133:2012, Ed. 2. *Medical electrical equipment: General requirements on basic safety and essential performance of Rechargeable Cells & Lithium Ion or Nickel*

Battery used in portable devices

- IEC 60601-1-2, Ed. 4, 2014. *Medical electrical equipment: General requirements on basic safety and essential performance on Electromagnetic Compatibility.*

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.

A risk analysis was also conducted for wireless coexistence testing per AAMI TIR 69, 2017, [Risk management of radio-frequency wireless coexistence for medical devices and systems](#). The Bose BMD-001 Hearing Aid uses standard 2.4GHz Classic Bluetooth and Bluetooth Low Energy (BLE) standards to communicate between the hearing aid and the user's Bluetooth enabled device. From the risk assessment, the temporary loss of Bluetooth communication from interfering RF signals is appropriately considered a negligible risk and according to AAMI TIR 69, wireless coexistence testing is not required. Note that the interruption of device control from the App would be similar to when the user is separated from their Bluetooth enabled device.

The Bose Hearing Aid contains a Bluetooth radio transmitter operating in the ISM band (2.400 to 2.4835 GHz) at less than 10 mW EIRP. The output power level at these operating frequencies of the Bose Hearing Aid was deemed sufficiently safe in terms of human exposure to nonionizing radiation for the intended use.

MECHANICAL PERFORMANCE

The Bose Hearing Aid device mechanical design was verified as summarized in the following table:

Table 3. Mechanical Performance Testing

Test Standard/Method	Test Purpose/ Description	Component (s) Tested	Acceptance Criteria	Results
Eartip Analysis - Previous Commercial Use	Memo concerning validation of StayHear+tips fit comfort, and conformance to IEC 60601-2-66	Bose Hearing Aid, StayHear+ tips	N/A	N/A
Neckband Fit Verification	To demonstrate that Bose Hearing Aid device is designed and manufactured to meet range of user anatomy (neckband opening and cord length) in accordance with 1988 Anthropometric Survey.	Bose Hearing Aid, StayHear + medium size tip + USB Power Supply	Meet neckband opening and cord length design to accommodate the 5th to 95th percentile range of user anatomy	All requirements and expected measurements were within specified range.

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.

ELECTROACOUSTIC PERFORMANCE

Electroacoustic testing with measurements and associated acceptance criteria at the system-level was performed on the Bose Hearing Aid as summarized in the Tables as follow, including per the applicable standards of *ANSI S3.22-2009 and ANSI/CTA 2051-2017*.

Table 4. Electroacoustic Performance Requirements for Bose Hearing Aid

Applicable Standards: ANSI CTA 2051:2017 (Clause) ANSI ASA S3.22:2009 (Clause)	Test	Acceptance Criteria	Result (Pass/Fail/ Complete)
CTA 2051 (4.1) Custom corrections for device may be used if CORFIG in standard is invalid	Custom Coupler Response for Flat Insertion Gain (CORFIG)	N/A*	Complete
CTA 2051 (4.1) Use Bose custom CORFIG for Bose Hearing Aid	Frequency Response Bandwidth	At least 250 Hz – 5 kHz**	Pass
ANSI S3.22 (6.2)	Maximum Acoustic Output	Less than or equal to 120 dB SPL**	Pass
ANSI S3.22 (6.11)	Output Distortion	Less than or equal to 5%**	Pass
CTA 2051 (4.4.2) Test frequency = 500 Hz Test input level = 100 dB SPL Gain adjusted for output = 80 dB SPL or, if not possible, for 100 dB SPL	Input Distortion	Less than or equal to 5%**	Pass
ANSI S3.22 (6.12)	EIN	Less than or equal to 32 dB SPL**	Pass
CTA 2051 (4.8)	Latency	Less than or equal to 15 ms**	Pass
CTA 2051 (4.7)	Estimated Battery Life	N/A*	Complete
ANSI S3.22 (6.3)	HFA-OSPL90	N/A*	Complete
ANSI S3.22 (6.5)	HFA-FOG	N/A*	Complete
ANSI S3.22 (6.7)	RTG	N/A*	Complete
CTA 2051 (4.10 – 4.17) Fixed or Level Dependent Frequency Equalization - Tone Control Level Dependent Gain/Compression SNR Enhancement Noise Reduction Feedback Control / Cancellation Personalization Device Coupling to the Ear Wireless Connectivity	Reporting of Hearing Aid Features	N/A *	Complete
N/A	Serial Number and Firmware are recorded	N/A*	Complete

*Acceptance criteria = N/A indicates reporting requirement, but not performance requirement

** As specified in applicable clause of CTA 2051

Test Standard/ Method	Test Purpose/ Description	Component (s) Tested	Acceptance Criteria	Results
Monaural / Binaural Directionality Verification	To demonstrate that Bose Hearing Aid device selects between Binaural and Monaural Directionality depending on the earbud don/doff state.	Bose Hearing Aid, StayHear + medium size tip + USB Power Supply	<ul style="list-style-type: none"> Room sound audible in both ears. Scratching sound present in left ear. Scratching sound present in right ear. Silence in right ear and room sound in left ear. Room sound only in left ear, no scratching. Silence in left ear and room sound in right ear. Room sound only in right ear, no scratching. 	All Passed

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.

USABILITY ENGINEERING

Requirements to analyze, design, verify and validate usability of the Bose Hearing Aid were developed and implemented to ensure that risks resulting from normal use and use errors are assessed and mitigated. This was formally evaluated in a Human Factors Study (please refer to Human Factors Testing section below for details).

In addition, The Bose Hearing Aid met the applicable requirements in IEC 60601-1-6:2010+A1:2013. *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability - Edition 3.1: Consolidated Reprint.*

BIOCOMPATIBILITY

The Bose Hearing Aid was tested in accordance with ISO 10993-1, FDA Guidance “*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*”, and the Bose risk management process.

The following table summarizes the testing results which indicate that the materials used in the device are safe for their intended use:

Table 5. Biocompatibility Testing of the Bose Hearing Aid

Component Tested	Test Requirement	Test Results
Bose Hearing Aid	MEM elution Cytotoxicity per <i>ISO 10993-5</i>	<i>Pass (Grade 0) - no evidence of causing cell lysis or toxicity</i>
	Tests for irritation per <i>ISO 10993-10</i>	<i>Pass (test score was 0.0 and 0.1)</i>
	Tests skin sensitization per <i>ISO 10993-10</i>	<i>Pass (no evidence of causing delayed dermal contact sensitization)</i>

All tests were passed and confirm that the Bose Hearing Aid met the requirement for biocompatibility.

REPROCESSING VALIDATION

The Bose Hearing Aid is provided non-sterile. The Earbud nozzles and Neckband may be wiped with a soft, dry cloth, and the StayHear+ tips may also be rinsed with warm water and thoroughly dried before attaching them to the earbuds. Liquid cleaners or solvents should not be used on any parts of the device because they may cause damage to the components.

SOFTWARE

The Bose Hearing Aid software consists of device firmware and mobile applications. The Bose Hearing Aid software is designed with ISO 13485 guidance, in compliance with the company's quality system requirements under risk management and software development and tested pursuant to *IEC 62304:2006+A1:2015*. Software documentation was submitted and reviewed using the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The Bose Hear mobile applications allow the parametric settings of the hearing aid to be adjusted. These settings are transmitted via Bluetooth to the Bose Hearing Aid into which the device firmware implements these desired changes.

The main elements of the software include:

- Device Firmware
- Mobile applications for iOS and Android

Software Description

Bose Hearing Aid Mobile Application(s)

This mobile application is designed to function with a user's compatible personal smartphone or tablet device. It is available for download on iOS or Android based systems from the Apple Store and Google Play store respectively. The Bose Hear mobile application is used to set and control audiological gain parameters as well as device settings on the Bose Hearing Aid.

Device Software Hazard Analysis

The submitted Bose Hearing Aid Risk Management File identifies software (and hardware) hazards associated with the device. This file contains detail on the following:

- nature of the hazardous event
- severity of the hazard
- cause(s) of the hazard
- method of control (e.g., alarm, hardware design)

- corrective measures taken, including an explanation of the aspects of the device
- design/requirements, that eliminate, reduce, or warn of a hazardous event; and
- verification that the method of control was implemented correctly.

Software Requirement Specification

A summary of software requirements related to the Bose Hearing Aid was submitted and found acceptable.

Traceability Analysis

A traceability matrix for the Bose Hearing Aid was provided in the submission that provides evidence of the safety-related requirements for the Bose Hearing Aid.

Verification and Validation

Key testing approaches, activities, testable configurations and verification responsibilities were conducted and documented. The software was verified using functional testing against requirements, unit tests and moreover, the clinical study validates that the self-fitting method functions as designed. Testing found no major defects for safety related features of the device software and firmware. The software is version controlled and the revision history is maintained. The latest version is 1.3.0 for the DSP firmware; versions 1.01.00 and 1.1 for the Mobile Droid App and the Mobile iOS App, respectively.

SUMMARY OF CLINICAL INFORMATION

The following is a summary of two clinical studies and a human factors study performed by the sponsor to support a reasonable assurance of safety and effectiveness for the Bose Hearing Aid.

The Bose Hearing Aid allows users to control and customize signal processing parameters to their hearing needs via the Bose user interface, which consists of two Dimension-Reduced Controllers (DRCs) (“Loudness” and “Fine Tuning”) implemented in an application running on a mobile device. Two clinical studies (Phase I and Phase II) and a human factors study were conducted to validate the self-fitting methodology for the Bose Hearing Aid.

Phase I Study: Laboratory Evaluation of Validity of Bose Self-Fitting Method

The Phase I study was a laboratory study with a simulated hearing aid on which the DRCs were implemented to determine the reliability and validity of the DRC method for user self-fitting of signal processing parameters. Fifty adult subjects (49 with mild to severe hearing loss, 1 with normal hearing) set the DRC under minimal supervision while listening to a variety of different recorded stimuli. The results demonstrated that 1) the Bose self-fitting method is reliable as the average test-retest error was 3.9 dB, which was within the 4 dB test-retest reliability of the probe microphone measurements used in real-ear verification of hearing aid fittings; 2) the Bose self-fitting method is valid as the average deviation from NAL-NL2 prescribed gain for subject-selected gain was 5 dB, which was in line with published reports of preferred gain settings after

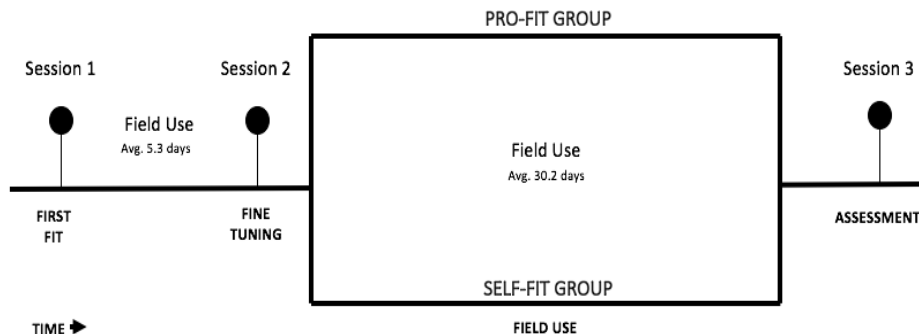
post-fitting fine tuning; and 3) the sound quality provided by the Bose self-fitting method is sufficient as the prescribed parameters were not significantly more preferred than the subject-selected ones. Overall, the Phase I study provides evidence that the Bose Self-Fitting method results in outcomes not inferior to professional fitting for adults with mild to moderate hearing loss.

Phase II Study: Clinical Validation of Bose Self-Fitting Method

Overall study design

A prospective, two-arm, pre-market study was conducted among 75 adult subjects with mild to moderately severe hearing loss to validate the effectiveness of the Bose Self-Fitting Method by comparing outcomes with self-fitting using the Bose DRCs to those with professional fitting of the same hearing aids. All subjects participated in three clinic visits (1-First Fit, 2-Fine-Tuning, and 3-Assessment) as well as several weeks of Bose prototype hearing aid use in the field (**Figure 4**). During the first two sessions, all subjects were fit professionally with a prototype version of the Bose Hearing Aid by one of several participating licensed audiologists using a custom professional fitting application. Subjects were then assigned for a one-month field trial to either a “Pro-Fit” Group (audiologist fit only, with limited program and volume control via mobile device, as would be the case for a typical professionally-fit hearing aid) or a “Self-Fit” Group (no access to audiologist fit, self-fit via Bose Hear mobile app implementing DRCs). In Session 3, all subjects returned to complete a speech-in-noise test as well as a series of questionnaires assessing benefit associated with the hearing aid. We note that the primary goal of the clinical studies was to validate the self-fitting strategy (DRCs), and patient self-selection was not directly evaluated. Individuals with normal hearing and individuals with severe to profound hearing loss were excluded from the study. Furthermore, in order to compare user-derived gain settings to professionally-(audiologist) derived settings within subjects, all subjects were fitted initially with the Bose Hearing Aid by an audiologist, including selection of the eartips. Thus, selection of the eartips was evaluated in a separate human factors study. The between-group design also enabled comparison between audiologist-based (Pro-Fit Group) and participant-based (Self-Fit) hearing aid fitting on multiple outcome measures as described below.

Figure 4. Experiment Timeline



Demographics

The table below provides information on subject demographics by group and analysis for the Phase II study.

Table 6. Subject Demographics

	All subs	
	Pro-Fit	Self-Fit
Sample Size	37	38
4FA AC Threshold (dB HL; mean, s.d.)	28.8 , 9.2	32.5 , 12.2
Sensorineural* (# participants)	30	34
Conductive* (# participants)	1	0
Mixed* (# participants)	1	1
Asymmetric† (# participants)	1	1
New Hearing Aid Users‡(# participants)	33	28
Experienced Hearing Aid Users‡ (# participants)	4	10
Age (years) mean, s.d.	62 , 13.4	66.1 , 12
Female (# participants)	19	20

*Conductive component if Air Bone Gap ≥ 15 dB at 500, 100, and 2000 Hz.

Study Results

Safety Results

The primary safety endpoint is evaluated by tabulations of Adverse Events (AEs) and Serious Adverse Events (SAEs). There were no AEs or SAEs occurring for any subject over the course of the study.

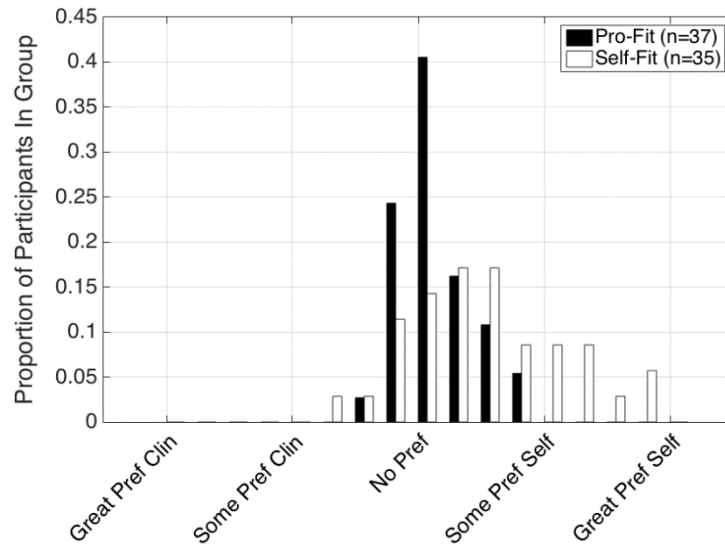
Effectiveness Results

Primary Endpoint

The primary effectiveness endpoint was the comparison of prescribed hearing aid settings versus DRC user-selected settings with respect to sound quality. The sound quality would be considered to be sufficient if the prescribed parameters were not significantly more preferred than the DRC-selected ones.

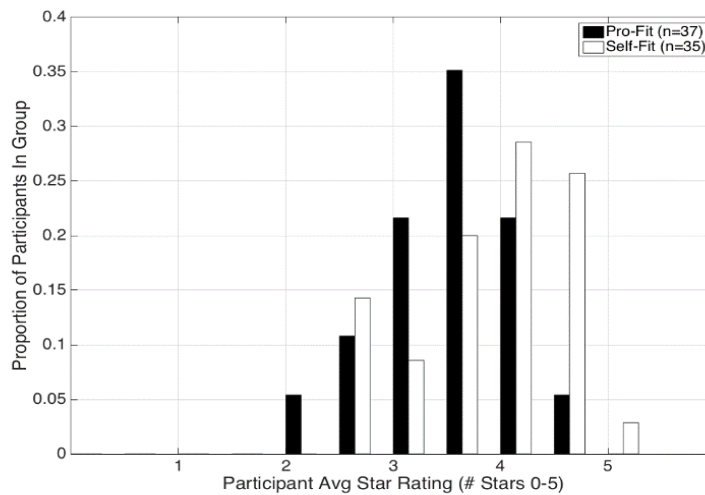
Subjects in the Self-Fit Group were satisfied with/preferred their own settings to the professionally-selected settings more than were/did subjects in the Pro-Fit Group. Subjects in the Self-Fit group preferred the set of signal processing parameters that they selected with the DRCs significantly ($p < 0.0001$) more than the set selected by the clinicians according to blind sound quality comparisons conducted in their everyday lives (**Figure 5a**).

Figure 5a. Distribution of subject average comparison scores plotted for Pro-Fit (black) and Self-Fit (white) Groups



The subjects in the Self-Fit Group rated themselves significantly happier with the sound quality than did those in the Pro-Fit group ($p < 0.0001$) (**Figure 5b**).

Figure 5b. Distribution of Star Ratings for the Pro-Fit (black) and Self-Fit (white) Groups



Secondary Endpoints

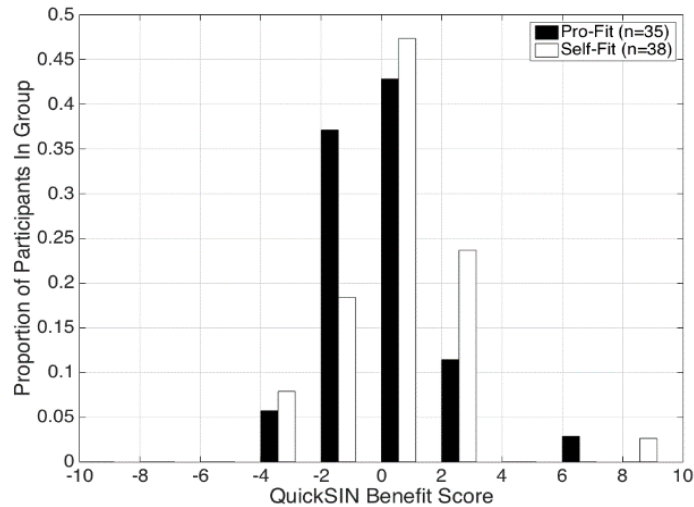
The secondary effectiveness endpoints were 1) objective benefit in speech-in-noise recognition performance (QuickSIN); and 2) patient-reported outcome measures captured by the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial, and Qualities of Hearing Scale for clinical use (SSQ-12) questionnaires.

Benefit, as measured by a speech-in-noise test (QuickSIN) and by two standard questionnaires

(APHAB & SSQ-12), experienced by the Self-Fit Group was significantly non-inferior to that experienced by the Pro-Fit Group.

There was no difference in speech intelligibility benefit between the Self-Fit and Pro-Fit Groups, as assessed by the QuickSIN. The analyses indicate that the QuickSIN benefit scores in the Self-Fit Group were significantly non-inferior to those of the Pro-Fit Group ($p < 0.05$) (**Figure 6a**).

Figure 6a. Distribution of QuickSIN Benefit Scores plotted for the Pro-Fit (Black) and Self-Fit (White) Groups



For the two patient-reported outcome measures (APHAB and SSQ-12), there was no difference in subject reported benefit between the Self-Fit and Pro-Fit Groups. Further analyses indicate that the benefit experienced by the Self-Fit Group was significantly non-inferior to that of the Pro-Fit Group, both in global and subscale ($p < 0.05$) (**Figures 6b and 6c**).

Figure 6b. Distribution of APHAB Global Benefit scores for the Pro-Fit (Black) and Self-Fit (White) Groups

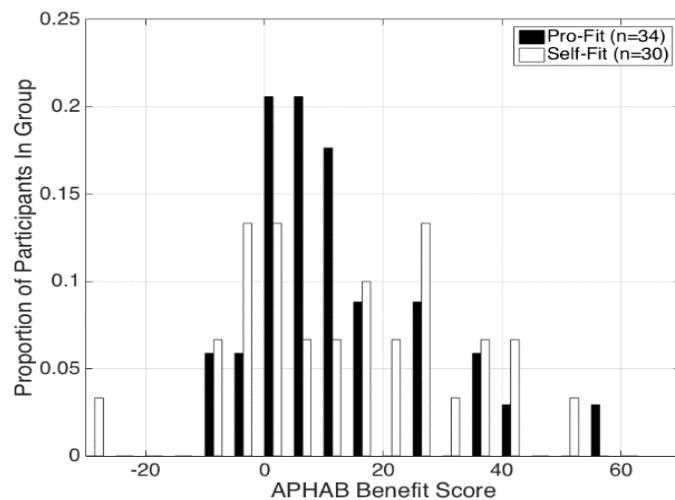
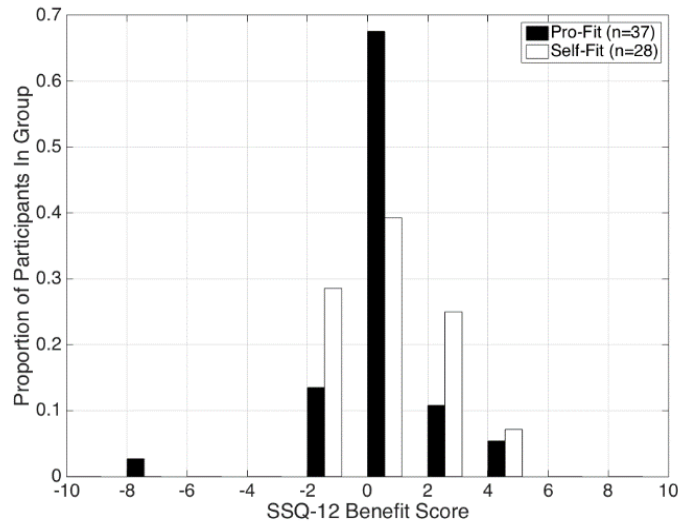


Figure 6c. Distribution of SSQ-12 benefit scores plotted for the Pro-Fit (Black) and Self-Fit (White) Groups

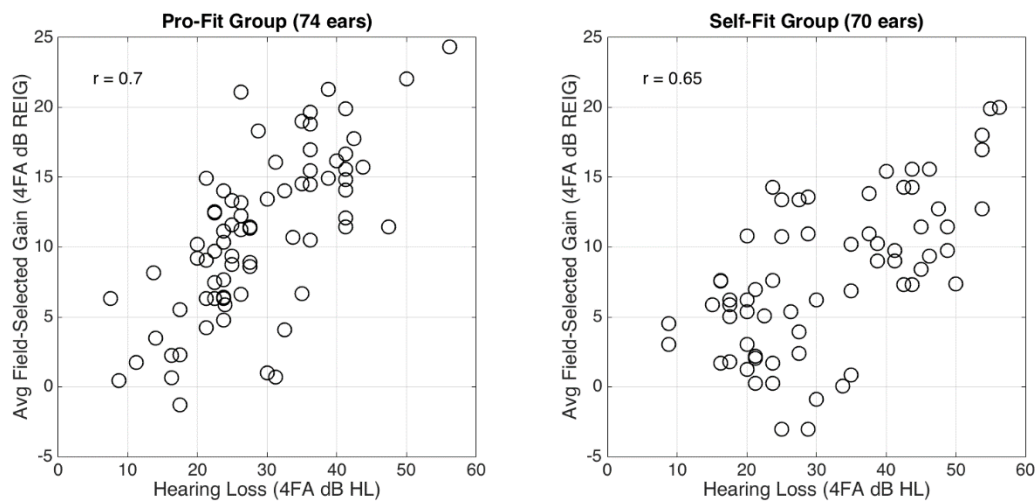


All primary and secondary effectiveness endpoints were met by the clinical validation study. These data support that the Bose Hearing Aid provides performance benefit consistent with that of the same hearing aid fitted by hearing professionals for individuals ages 18 and older with mild to moderate hearing loss.

Additional Effectiveness Measures

Subject-selected gain (DRC derived) was significantly correlated with professionally-selected gain ($r = 0.65$, $p < 0.0001$) and subject-selected gain was on average only 1.9 dB less than professionally-fit and fine-tuned gain, indicating that the subject-selected gain settings were appropriate for subjects' hearing loss and comparable to a professionally derived fitting (**Figure 7**).

Figure 7. Correlation between Hearing Loss (x) and Field-Selected Gain (y) plotted separately for Pro-Fit (left) ($r = 0.70$, $p < 0.0001$) and Self-Fit (right) ($r = 0.65$, $p < 0.0001$) groups



Pediatric Extrapolation

The Bose Hearing Aid is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Federal Food, Drug, and Cosmetic Act defines pediatric patients as persons aged 21 or younger. In this De Novo request, existing clinical data were not leveraged to support the use of the device in individuals younger than 18 years old.

HUMAN FACTORS TESTING

The Bose Hearing Aid is intended to be used by users without prior hearing evaluation, prescription, or fitting by a professional. In addition to the clinical validation study, a human factors study was conducted to ensure its intended direct-to-consumer use, without involvement of a hearing professional. The human factors study included 20 adult subjects with perceived mild to moderate hearing loss who performed tasks with the Bose Hearing Aid in simulated use environments. These tasks included two critical tasks related to sound awareness safety and the need for hearing protection in loud listening environments, as well as an assessment of the ability to select the correct eartips. The usability tasks also included:

- Charging the Bose Hearing Aid
- Selecting appropriate eartip size from 3 provided
- Powering on the HA and donning it
- Downloading the Bose Hear mobile app
- Pairing the HA with a mobile device running the Bose Hear app
- Using app and on-device controls to adjust settings and establish settings for listening in different environments
- Listening to streamed audio content

- Powering off the HA
- Minor maintenance tasks such as recharging batteries, etc.

Overall, the human factors study demonstrated that the usability of the Bose hearing aid was analyzed, verified, and validated for its intended use, and the implemented mitigations for user training and device labeling are adequate. The user instructions and training materials were successful in allowing users to complete the appropriate tasks.

In summary, for this population, the following conclusions can be made from the clinical validation and human factors studies:

- The Bose Hearing Aid DRCs are effective for selecting wide dynamic range compression (WDRC) parameters
- The Self-Fit (user-derived) settings were preferred over the Pro-Fit (audiologist-derived) settings on average
- Benefits measured using standard measures were not inferior for the Self-Fit (user-derived) settings compared to the Pro-Fit (audiologist-derived) settings on average
- Intelligibility of speech in noise was not reduced by using DRCs (Self-Fit) to derive use settings on average
- Average gain selected by users using the DRCs to self-fit is similar to that selected by a professional using best practices
- Users are able to use the Bose Hearing Aid appropriately and select the proper eartips

LABELING

The sponsor provided labeling information which includes Instructions for Use (i.e., User Manual). The Instructions for Use includes information on how a patient can self-identify as a candidate for the device, when to seek professional help, and cautions about using hearing protection in loud environments and staying alert to sounds around the user of the device. Technical data for the device and information about the return policy will be made available to users either via the manufacturer's website or in a separate user information document.

The labeling is sufficient and satisfies the applicable requirements of 21 CFR 801.420, *Hearing aid devices; professional and patient labeling*.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a self-fitting air-conduction hearing aid and the measures necessary to mitigate these risks.

Table 7. 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

SPECIAL CONTROLS:

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.

BENEFIT/RISK DETERMINATION

The Bose Hearing Aid's probable risks have been adequately mitigated, as demonstrated by successful non-clinical and clinical performance testing, including a lack of adverse events in the clinical validation studies and user errors in the human factors study. Potential risks associated with device use are identified above. Some of these risks are based on events known to occur in other air-conduction hearing aids as documented in the MAUDE (Medical Device Report) database. These risks may occur more frequently in the broader intended population than were observed in the study population. However, the clinical validation and human factors studies, along with a review of the device specifications and non-clinical testing, strongly supports the safety of the Bose Hearing Aid. There is a high likelihood that risks are mitigated and users would typically experience only non-serious adverse events which would be reversible by modification or removal of the device.

The probable benefits of the device are based on data collected in the clinical studies as described above. The measured clinical benefits for these subjects, ages 18 years and older, with mild to moderate hearing loss are highlighted in the primary and secondary endpoints and served to show that a user can derive their own Bose Hearing Aid settings that are comparable to professionally (audiologist) derived settings with respect to the amount of gain, understanding speech in noise, and subjective benefit. The Phase I clinical study demonstrated that the Bose Self-Fitting method results in outcomes not inferior to professional fitting for adults with mild to moderate hearing loss. The Phase II clinical study demonstrated that 1) user-selected gain was

significantly correlated with professionally-selected gain and user gain was on average only 1.9 dB less than professional, indicating that the self-selected gain settings were appropriate for subjects' hearing loss and comparable to a professionally derived fitting; 2) benefit experienced by the Self-Fit Group was significantly non-inferior to that experienced by the Pro-Fit Group as measured by two standard questionnaires (APHAB & SSQ-12) and by a speech-in-noise test (QuickSIN) test; and 3) subjects in the Self-Fit Group were satisfied with/preferred their own settings to the professionally-selected settings more than were/did subjects in the Pro-Fit Group. The human factors study demonstrated that the usability of the Bose hearing aid was analyzed, verified, and validated for its intended use, and the implemented mitigations for user training and device labeling are adequate. The technology in the Bose Hearing Aid that allows it to be effectively fit, customized, and used without the involvement of a hearing healthcare professional provides additional options for patients with perceived mild to moderate hearing loss.

Patient Perspectives

Patient perspectives considered for the Bose Hearing Aid during the review include: 1) blind A/B comparisons of the user-derived listening settings with the professionally-derived listening settings, 2) patient-reported outcome measures captured by the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial, and Qualities of Hearing Scale for clinical use (SSQ-12) questionnaires, and 3) patient satisfaction and preferences for the user-derived settings over the professionally-derived settings.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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.

The probable benefits outweigh the probable risks for the Bose Hearing Aid. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Bose Hearing Aid is granted and the device is classified as follows:

Product Code: QDD
Device Type: Self-fitting air-conduction hearing aid
Regulation Number: 21 CFR 874.3325
Class: II