December 21, 2022

Eargo, Inc.
Monica Barrett
Sr. Dir. RAQA
2665 North First Street, Suite 300
San Jose, California 95134

Re: K221698
Trade/Device Name: Eargo Self-Fitting Hearing Aids
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: November 21, 2022
Received: November 22, 2022

Dear Monica Barrett:

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,

Joyce C. Lin -S

for 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)*
K221698

Device Name
Eargo Self-Fitting Hearing Aids

Indications for Use *(Describe)*
The Eargo Self-Fitting Hearing Aids are intended to amplify and transmit sound to the ear and thereby compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The product is intended to be used without the assistance of a hearing care professional.

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

510(k) Applicant
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Date of Summary: 12 December 2022

Trade Name: Eargo Self-Fitting Hearing Aid Family of products
Models: Eargo 5, Eargo 6
Common Name: Self-Fitting Air-Conduction Hearing Aid, Over The Counter
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulation Number: 21 CFR 874.3325
Product Code: QUH
Classification: Class II

Panel: Ear Nose & Throat

- PREDICATE DEVICE

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K211008	Bose SoundControl™ Hearing Aids	Bose Corporation

- DEVICE DESCRIPTION

The Eargo Self-Fitting Hearing Aid is a self-fitting air-conduction hearing aid system that incorporates wireless technology in its programming and use. The hearing aid system consists of a pair of earbud-style hearing aids (left and right), a charging case, and a companion mobile application (app) available for iOS (version 12 or later) and Android (version 7 or later) mobile devices. The hearing aids are designed to be virtually invisible, inserted completely and discreetly within the ear canal. Each hearing aid contains a microphone to allow for audio input, which is amplified by the hearing aid. The mobile

app facilitates Eargo's proprietary self-fitting process using a combination of proprietary ultrasonic (for fitting) and Bluetooth Low Energy (BLE; for programming fitting settings) wireless communication. The mobile app also allows the user to control the hearing aids using proprietary ultrasonic wireless communication and enables firmware updates to the hearing aid system via BLE. App-based user controls include program and settings changes. In addition, each hearing aid contains an accelerometer sensor that allows for on-device user control of the hearing aids. On-device user controls allow the user to make program changes without the mobile app. Each hearing aid contains a rechargeable Li-ion battery and is charged by the charging case that also functions as a carrying case. The charging case contains a single-cell Li-ion rechargeable battery, which charges the hearing aids via wireless (near-field inductive) charging when the hearing aids are correctly placed into the charging case.

Figure 1: Eargo Self-Fitting Hearing Aid Communication Pathways

- INTENDED USE

The Eargo Self-Fitting Hearing Aids are intended to amplify and transmit sound to the ear and thereby compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older.

- INDICATIONS FOR USE

The Eargo Self-Fitting Hearing Aids are intended to amplify and transmit sound to the ear and thereby compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The product is intended to be used without the assistance of a hearing care professional.

- SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Both the Eargo Self-Fitting Hearing Aids (subject device) and the predicate device, the Bose SoundControl™ Hearing Aid (K211008), are self-fitting wireless air-conduction sound amplifying devices intended to compensate for perceived impaired hearing in individuals aged 18 years and older. Both the subject and predicate devices incorporate technology that integrates user input with a self-fitting strategy that enables users to independently derive and customize their hearing aid fitting and settings.

Both the subject and predicate devices share the following similar technological characteristics:

- Mobile app-based (wireless) self-fitting strategy
- Acoustic performance adequate for the intended use
- Mobile app-based (wireless) and on-device user controls for fitting and customization
- Mobile app-supported (wireless) system firmware updates
- Different sized eartips in open and closed styles
- Acoustic performance features (noise reduction, feedback cancellation)

The Eargo Self-Fitting Hearing Aids include the following:

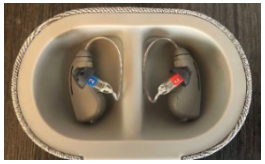
- Completely in the canal (CIC) form factor with single omnidirectional microphone
- Independent treble, bass, and noise reduction user controls
- Independent left and right hearing aid customization
- Rechargeable hearing aids

- Rechargeable charger case
- Proprietary ultrasonic wireless communication to hearing aids

Table 1 discusses the comparison between the Eargo Self Fitting Hearing Aid (subject device and the Bose SoundControl™ Hearing Aid (predicate device)

Table 1: Comparison

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Device Type	Self-fitting air conduction hearing aid	Self-fitting air conduction hearing aid	The device type is the same as the predicate.
Indications for Use	Eargo Self-Fitting Hearing Aids are intended to amplify and transmit sound to the ear and thereby compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The product is intended to be used without the assistance of a hearing care professional.	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. They are 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 indications for use are similar to the predicate except for the last sentence. The difference in the final sentence does not raise different questions of device safety and effectiveness.
Intended Use	The Eargo Self-Fitting Hearing Aid are intended to amplify and transmit sound to the ear and thereby compensate for perceived mild to moderate hearing impairment in individuals 18 years of age or older.	The 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.	The intended use is the same as the predicate.
Technology	Self-fitting air conduction hearing aid incorporating wireless technology	Self-fitting air conduction hearing aid incorporating wireless technology	The technology is the same as the predicate.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Form Factor	Traditional CIC (completely in canal) form factor. Non-custom, separate left and right ear units. User-replaceable eartips come in different sizes. 	Traditional receiver in the canal (RIC) and behind the ear (BTE) form factor. Non-custom, separate left and right ear units. User-replaceable eartips come in different sizes. Factory replaceable wire cable comes in different sizes. 	The subject device form factor is a wireless CIC and the predicate device form factor is a RIC/BTE with wired earbuds, data from biological safety testing, usability testing, and clinical validation data support substantial equivalence with the predicate device.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Wireless Communication: Mobile app (via smartphone/mobile device) to hearing aid system	Wireless communication between the mobile app and the hearing aid system occurs in two ways: 1) Mobile app to hearing aids: Wireless communication from the mobile app to the hearing aids is done via a proprietary Eargo UltraSonic (EUS) communication protocol. App to hearing aid communication via EUS supports Sound Match self-fitting, and program and settings changes to the hearing aids. 2) Mobile app to charger case: Wireless communication from the mobile app to the charger case is done via 2.4GHz Bluetooth 5.0 Low Energy (BT5.0 LE). App to charger case communication via BT5.0 LE supports hearing aid programming, system info recognition by the app, and delivering firmware updates to the hearing aid system.	Wireless communication between the mobile app and the hearing aids occurs via the 2.4GHz Bluetooth Low Energy (BLE) standard. App to hearing aid communication via BLE supports self-fitting (i.e., listening mode and settings changes) and firmware updates.	Wireless (app-based) user controls of the subject device, such as self-fitting, program and setting changes etc. are achieved via EUS. Additional app-based user controls related to programming, recognizing, and updating the hearing aids are facilitated by a BT5.0 LE connection between the app and the charger. The technological differences of the subject device + mobile product/App (using EUS) versus the predicate + mobile device/its App (using Bluetooth LE) are supported by usability testing of the subject device. This usability testing demonstrated both user satisfaction and ease of use for EUS control of the Eargo hearing aids. While the communication protocols differ between the subject and predicate devices, the overall wireless-supported functions and connectivity/electrical safety risks are similar and do not raise different questions of device safety and effectiveness.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Bluetooth Pairing and Control	Pairing, control, and verification with the paired mobile device are done via the charger case.	Pairing, control, and verification with the paired mobile device are done via the hearing aids.	While the pairing process differs between subject and predicate devices, they are using the same technology. These differences do not raise different questions of safety and effectiveness. Data from wireless performance testing support substantial equivalence.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Battery	Eargo Self Fitting Hearing Aids are rechargeable, with the hearing aids charged inside a proprietary portable charger case via wireless (near-field inductive) charging. The charger case contains a Li-ion battery that provides up to 3 hearing aid use cycles (for a pair of hearing aids) on a single full charge, depending on use. The charging case supports both self-powered operation and/or being powered by a standard USB-C cable connected to a power supply. When connected to a USB power supply, the internal battery is recharged, allowing for subsequent on-the-go charging of hearing aids. Eargo hearing aids house a small capacity secondary type (rechargeable) Li-Ion battery that is certified to IEC 62133-2:2017. The battery allows for up to 16 hours of runtime, depending on use.	Bose SoundControl Hearing Aids require single-use Size 312 primary type (non-rechargeable) Zn-Air batteries.	The subject device is rechargeable between use cycles, while the predicate device uses replaceable batteries. The differences in battery type and capacity do not raise different questions of safety or effectiveness. Data from battery safety testing support substantial equivalence.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Microphones	Subject device CIC hearing aids each contain a single omnidirectional microphone to allow for acoustic input.	Predicate device BTE hearing aids contain microphones that may, during use, be configured by the user in omnidirectional or directional modes.	The predicate device has a RIC/BTE form factor with two microphones that can be configured in omnidirectional or directional modes. The subject device has a single omnidirectional microphone not configurable by the user. The subject device though is completely in canal (CIC) style hearing aid allowing the user to use natural pinna cues for directionality. Clinical validation data support substantial equivalence with the predicate device.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
User/Device Controls	On-device user controls: - User-selectable Programs/Environments (i.e., Eargo-recommended gain offsets). App-based user controls: - Volume - Mute - Treble and bass (independent adjustment) - Left/Right/Both (independent adjustment) - Program/Environment (user-customizable Eargo-recommended gain offsets) - Noise Filter adjustment - Bluetooth pairing with Eargo Charger	On-device user controls: - Power on/off - World Volume App-based user controls: - World Volume - Treble and bass (balance adjustment) - Focus (mic directionality) - Left/Right (balance adjustment) - Modes (Bose-recommended gain profiles, user-customizable) - Bluetooth pairing with hearing aids	The combined suite of on-device and app-based user controls of hearing aids are comparable between the subject and predicate devices. The predicate device's "Focus" feature is specific to the microphone configuration of its RIC/BTE form factor, which benefits from the ability to change directionality modes. The subject device's CIC form factor utilizes an omnidirectional microphone configuration that sits within the ear canal when inserted into the ear and leverages the natural directional characteristics of the head and pinna during normal use. Other differences in feature implementation and adjustability do not raise different questions of safety and effectiveness.
Over The Air (OTA) Firmware Update	The hearing aids automatically update when connected to the mobile app. The Eargo Mobile app allows for remote firmware update of the hearing aids.	The hearing aids automatically update when connected to the mobile app.	The firmware update process is the same as predicate.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Compression	The subject device uses 8-channel wide dynamic range compression (WDRC).	The predicate device uses 12-channel wide dynamic range compression (WDRC).	The 8-channel WDRC settings in the subject device and the 12-channel WRDC settings in the predicate device operate across similar overall frequency/bandwidth ranges, and both allow only gross adjustments to spectral tilt via bass and treble controls. This difference does not raise different questions of safety and effectiveness. Data from a clinical validation study support substantial equivalence.
Noise Reduction	The subject device utilizes a fast-acting noise reduction algorithm to reduce noise between sentences, words and syllables & to improve speech perception when background stationary/steady-state noises (such as vacuum cleaners, air conditioners, etc.) are present. This feature is user adjustable.	The predicate device utilizes a noise reduction approach when steady-state noises are detected.	Noise reduction is the same as the predicate.
Feedback Cancellation	The subject device utilizes a feedback canceller.	The predicate device utilizes a feedback canceller.	Feedback cancellation is the same as the predicate.

Feature/ Attribute	Eargo Self Fitting Hearing Aid (Subject Device)	Bose SoundControl™ Hearing Aid (Predicate Device)	Discussion
Self-Fitting Method	The Eargo Self-Fitting Hearing Aid uses a proprietary method that requires the user to complete a self-guided hearing assessment using the mobile app while wearing the hearing aids. The hearing aids act as the transducer, emitting tonal stimuli of varying levels at different audiometric frequencies. The measured hearing thresholds are then used as the basis for fitting the appropriate gain profile(s) for the user. Once fitted, the user can make additional adjustments (e.g., volume, bass/treble) to the left, right, or both hearing aids to achieve a desired fitting.	The predicate device utilizes a proprietary fitting approach that does not require determination of hearing thresholds. Each user starts with the same settings and adjusts settings (e.g., volume, bass/treble, left/right balance) based on the user's preference and the listening environment to achieve a satisfactory fitting.	Both the subject and predicate devices use proprietary fitting algorithms. While the basis for self-fitting differ in that the subject device uses an approach based on hearing thresholds and the predicate device uses an approach based on user preference, both are intended to provide adequate fitting for individuals with perceived mild to moderate hearing impairment. Clinical and usability data demonstrate that the subject device's self-fitting approach is able to deliver hearing aid output comparable to NAL-NL2 prescription targets. Thus, the subject device provides adequate amplification for individuals with mild to moderate hearing impairment, just as the predicate device does.

Any differences in technological characteristics between the subject and predicate devices do not carry any impact to the subject device's intended use, and do not raise different questions of safety or effectiveness. Testing against common industry performance standards and demonstrated equivalence in functional performance testing indicate that the subject device is substantially equivalent to the predicate device for the same intended use.

- SPECIAL CONTROLS

The Eargo Self-Fitting Hearing Aids conform to the special controls stated in 21 CFR 874.3325. The requirements are satisfied through:

- Labeling
- Performance testing
- Clinical data
- Usability testing/human factors validation

- SELF-SELECTION LABELING

Self-Selection labeling mitigating the risk of improper self-selection has been included in the Quick Start User Guide and the Full-Length User Guide for Eargo Self-Fitting Hearing Aids. In summary, the self-selection labeling addresses:

- Identifying situations in which the Eargo Self-Fitting Hearing Aids may help users hear better.
- Identifying situations in which the Eargo Self-Fitting Hearing Aids may not be right for users.
- Identifying criteria for which users should see a hearing professional.
- Informing users that Eargo Self-Fitting Hearing Aids will not restore normal hearing.
- Informing users that it is good health practice to have hearing loss evaluated by an appropriate health care professional.

- PERFORMANCE TESTING

See **Table 2** & **Table 3** below.

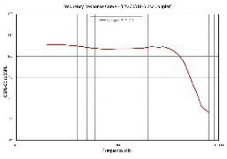
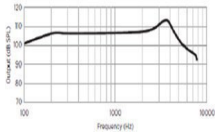
Table 2: Safety Compliance Testing Summary

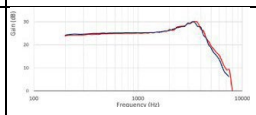
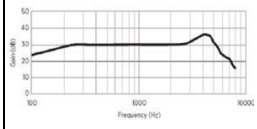
Compliance / Testing Standard(s) / FDA Guidance	Test Purpose	Result
FCC Title 47 CFR, subpart 15 subpart C Intentional Radiators	Basic Safety and Essential Performance	Pass
IEC 60601-1:2014 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Basic Safety and Essential Performance	Pass
IEC 60601-2-66: 2019 Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems	Basic Safety and Essential Performance	Pass
IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	Electromagnetic Compatibility	Pass
IEC 60118-13:2019 Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility	Electromagnetic Compatibility	Pass
ANSI ASA S3.22:2014 – Specification of Hearing Aid Characteristics	Electroacoustics Performance	Pass
• IEC 62304:2006 – Medical device software – Software lifecycle processes • FDA Guidance FDA-2020-D-0957 - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - May 11, 2005	Software Verification and Validation	Pass

Compliance / Testing Standard(s) / FDA Guidance	Test Purpose	Result
• ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity • ISO 10993-10:2010 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization • ISO 10993-12:2010 - Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials • FDA Guidance FDA-2013-D-0350- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process" - September 4, 2020	Biocompatibility	Pass
• IEC 62366:2007 + A1:2014 – Medical devices – Part 1: Application of usability engineering to medical devices • IEC 60601-1-6:2010 + A1:2013 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability • FDA Guidance FDA-2011-D-0469 - Applying Human Factors and Usability • Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff - February 3, 2016	Summative Usability / Human Factors Validation	Pass

Compliance / Testing Standard(s) / FDA Guidance	Test Purpose	Result
• FDA Guidance FDA-2018-D-3443 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - October 18, 2018 • FDA Guidance FDA-2015-D-5105 - Postmarket Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - December 28, 2016	Cybersecurity Compliance	Pass
• ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems • ASTM D7386-16 Standard Practice For Performance Testing Of Packages For Single Parcel Delivery Systems	Package and Transit Testing	Pass

Table 3: Electroacoustics Performance (ANSI/ASA S3.22 2014 Measurements or ANSI/CTA-2051:2017 where denoted by *)

Characteristics	Eargo Self Fitting Hearing Aids (Subject Device)	Bose SoundControl Hearing Aid (Predicate Device)	Discussion
OSPL 90 Curve			Comparable to predicate device and suitable for intended use.
MAX OSPL 90	106 dB SPL which is less than 117 dB SPL"	113 dB SPL which is less than 120 dB SPL	Comparable to the predicate device and less than 117dBSPL per OTC hearing aid requirements.

Characteristics	Eargo Self Fitting Hearing Aids (Subject Device)	Bose SoundControl Hearing Aid (Predicate Device)	Discussion
HFA OSPL 90	104 dBSPL	106 dBSPL	Comparable to predicate device and adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2.
HFA FOG	26 dB	30 dB	Comparable to predicate device and adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2.
Reference Test Gain (RTG)	26 dB	29 dB	Comparable to predicate device and adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2.
Frequency Response			Comparable to predicate device and suitable for intended use.
Frequency Range	<200 - 7500 Hz	<200-8000 Hz	Comparable to predicate and suitable for intended use per OTC hearing aid requirements.
Harmonic Distortion (%)	< 1%	< 1%	Same as the predicate device and per OTC hearing aid requirements.
EIN	< 30 dBSPL	<27 dBSPL	Less than or equal to 32 dBSPL. Comparable to predicate device and per OTC hearing aid requirements.

Characteristics	Eargo Self Fitting Hearing Aids (Subject Device)	Bose SoundControl Hearing Aid (Predicate Device)	Discussion
Battery Current	0.56mA	2.8mA	Eargo Self-Fitting Hearing Aids use a custom rechargeable li-ion battery, whereas the predicate device uses replaceable zinc batteries.
Latency*	5.7ms	5.5ms	Comparable to predicate device and less than or equal to 15ms per OTC hearing aid requirements.

- CLINICAL DATA

Clinical studies across three geographically disparate U.S sites were conducted to validate the self-fitting strategy of the Eargo Self-Fitting Hearing Aid. The studies focused on 1) validating the accuracy of audiometric thresholds measured with Eargo's Sound Match feature against the audiometric thresholds measured by an audiologist following audiology best practice methods, and 2) validating the effectiveness of Eargo's self-fitting approach in a clinical trial comparing self-fitting hearing aid outcomes to the same hearing aid fit by an audiologist following clinical best practice methods for fitting hearing aids. Outcome measures - comparing the two fitting methods - included: subjective hearing aid benefit with in-field device wear, real-ear aided response, lab-based measures of subjective sound quality, and speech intelligibility in noise.

Finally, Eargo also administered a sound quality satisfaction survey to hearing impaired individuals who have used Eargo devices (hearing aids and the mobile-app) in the field (i.e., real-world situations) for two months or longer.

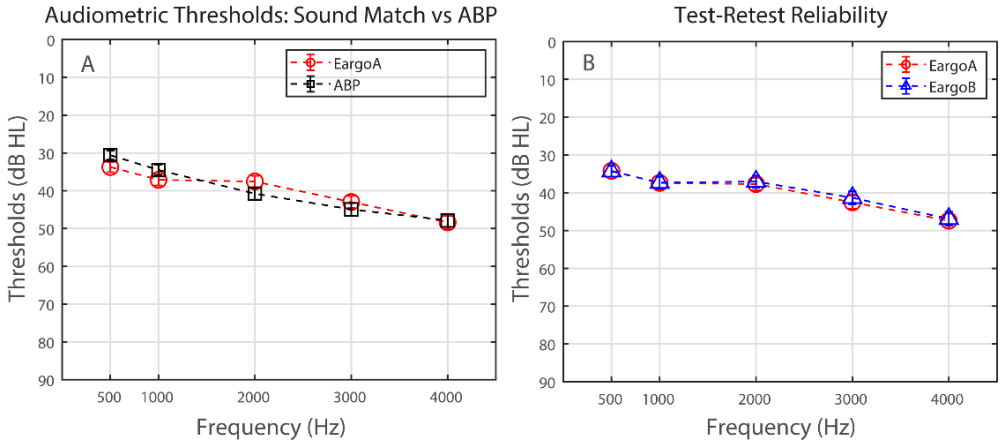
Clinical Validation of Eargo's Sound Match Hearing Thresholds Against Audiology Best Practice

To validate the accuracy of Sound Match, Eargo's proprietary, app-based method for self-determining audiometric thresholds, Eargo collaborated with the University of the Pacific (San Francisco and Stockton campuses) to conduct a study involving hearing impaired and normal hearing subjects. One hundred subjects (76 with hearing loss), 18 years of age or

older, participated in the study. Subjects varied in age (ranging from 22 - 99 years), gender (52 female and 48 male) and degree of hearing loss.

Subjects were tested across three conditions: 1) air-conduction audiometric thresholds obtained by an Audiologist in a sound-treated booth, following Audiology best practice methods (ABP), and 2) subject-determined air-conduction audiometric thresholds using Eargo Sound Match in a sound-treated booth (EargoA) and 3) in a quiet room (EargoB). 100 subjects completed the ABP and EargoA conditions, and 91 subjects completed the EargoB condition. Overall, EargoA thresholds were comparable to ABP across all frequencies tested (**Figure 2 - Panel A**). Pairwise t-test showed no statistically significant differences between EargoA thresholds and clinical thresholds at all frequencies tested. With respect to test-retest reliability, thresholds were comparable between EargoA and EargoB across all frequencies tested (**Figure 2 - Panel B**). Pairwise *t*-test showed no statistically significant differences between EargoA and EargoB thresholds.

Figure 2: Comparing audiometric thresholds measured with Sound Match vs Audiology Best Practice. Panel A – Comparing averaged thresholds (across both ears and all the subjects) measured at different frequencies between EargoA (in red) and ABP (in black). **Panel B** - Comparing averaged thresholds (across both ears and all the subjects) measured at different frequencies between EargoA (in red) and EargoB (in blue).



Eargo Sound Match was also evaluated with the System Usability Scale (SUS), and the mean overall SUS score was 71, which compares favorably to the industry benchmark of 68. This suggests that subjects were able to easily and independently self-measure audiometric thresholds using Eargo's Sound Match feature.

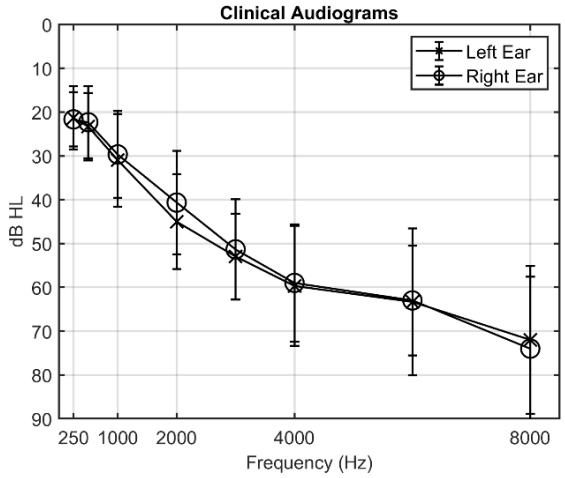
These results strongly suggest that audiometric thresholds self-measured by subjects using Eargo's Sound Match feature are comparable to the air-conduction hearing thresholds

measured by Audiologists following audiology standard of care, and therefore can be an effective basis for self-fitting.

Clinical Verification of Eargo's Self-Fitting Approach

A clinical trial was conducted at the Center for Applied and Translational Sensory Science at the University of Minnesota to validate Eargo's self-fitting approach. 33 subjects (18 female, 15 male), aged between 24 to 83 years, with predominantly mild-to-moderate hearing loss in both ears participated in the study. 14 subjects had prior experience with hearing aid use. Inclusion criteria for participation included sensorineural hearing loss in both ears from .25-4 kHz, with the cutoff threshold of 65 dB at these frequencies. Mean audiograms for left and right ears for the 33 participants are shown in **Figure 3**.

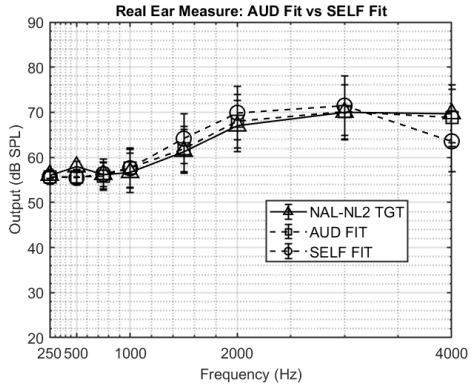
Figure 3: Mean audiometric thresholds for 33 participants for left and right ears.



Each participant completed 3 separate testing visits. A within-subject, crossover design in which all participants completed both field trial hearing aid fitting conditions (self-fit and audiologist-fit hearing aids) was used. The order of the field trials was randomized across participants to account for any potential order effects. After each field trial, participants visited the lab to complete study outcome measures. The participants wore devices for each fitting condition for 2-3 weeks in the field and were blinded to the fitting approach. At the initial visit, the participants completed a standard clinical hearing test as well as self-measured their hearing thresholds using Eargo's Sound Match feature. Consistent with the results shown in **Figure 2**, no significant differences were noted between thresholds measured using the clinical best practice methods and Eargo's Sound Match feature.

In the audiologist-fit condition (AUD-fit), a research audiologist used clinical best practice methods to match Real Ear Aided Response (REAR) to NAL-NL2 targets from .25-4kHz within 3 dB of the target gain. All programming changes were made using Eargo Fitting Software. Participants were given the option to make requests for further adjustments based on subjective complaints. REAR was recorded after adjustments. In the self-fit condition, the thresholds measured using Eargo's Sound Match feature were first mapped to an audiogram from a pre-populated list. Hearing aid fitting parameters (based on a proprietary fitting formula) were loaded into the devices based on the measured thresholds. Participants were given the option to self-adjust the treble, bass, and overall volume of the hearing aids using the accompanying Eargo app. REAR measurement was recorded after the participants made adjustments using the app. All real-ear measures were recorded using the International Speech Test Signal (ISTS) at 65 dB SPL. No significant differences were noted between real-ear gain measured between self-fit and AUD-fit settings, as shown in **Figure 4**. Average Root Mean Square Error (RMSE) from NAL-NL2[1] targets at 250 Hz, 1 kHz, 2 kHz and 4 kHz were below 5 dB for both fitting conditions. An RMSE criterion of 5dB from prescriptive targets has been the precedent in academic research and is attainable for most mild to severe hearing losses.

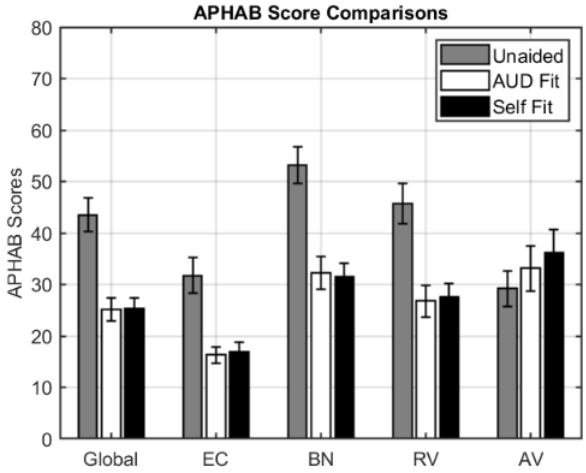
Figure 4: Mean REAR comparisons between the fitting approaches. Comparison of average self-fit and AUD-fit for a 65-dB SPL male talker. Mean and standard deviations are shown for 33 participants.



All participants completed the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire[2]. The objective of the APHAB measure was to confirm that performance outcomes for the self-fit condition were not inferior to those from the same devices fit by an audiologist (AUD-fit) after a period of hearing-aid use in everyday listening conditions. The primary endpoint was the APHAB-global score. Participants completed the questionnaire at the time of recruitment (unaided) and following each of the two field

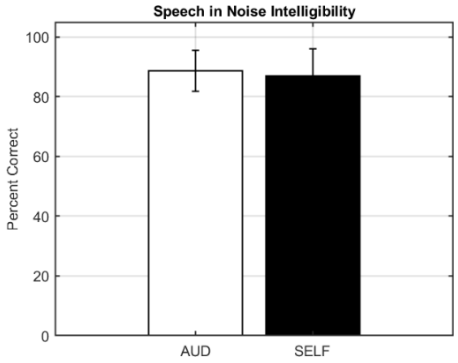
trial conditions (self-fit and AUD-fit). Results showed very similar aided mean and standard deviation values for self-fit, and AUD-fit across APHAB subscales and the overall APHAB-global score demonstrating substantial equivalence between the two fitting approaches (see **Figure 5**). On all three subscales assessing speech communication (Ease of Communication - EC, Background Noise - BN and Reverberation - RV) and the global score, mean scores were significantly improved over the unaided condition for both self-fit and AUD-fit. Overall, the APHAB results from this study are in agreement with those reported for the Bose predicate device study[3].

Figure 5: Raw APHAB scores for unaided, self-fit and AUD fit. Mean and standard error bars are shown for 33 participants.



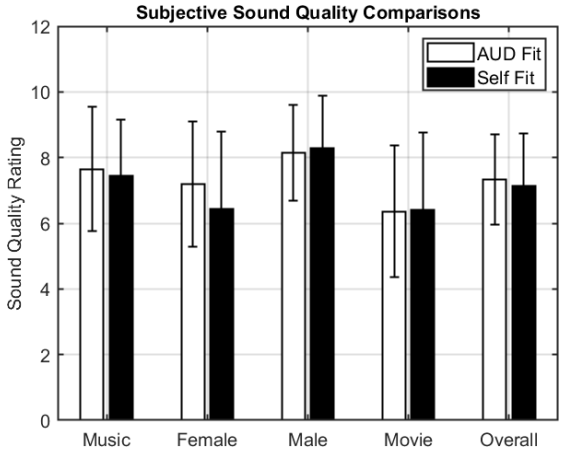
Another primary endpoint, aided speech in noise understanding was measured using AzBio sentences in a sound treated booth for both AUD-fit and self-fit conditions. The speech was presented at 65 dB A and pink noise was presented at 60 dB A (+5 dB SNR). Results were scored as a percentage of words correct. **Figure 6** shows speech recognition in noise scores for self-fit and AUD fit. Results showed very similar mean and standard deviation values when comparing the aided speech in noise scores for the two fitting approaches.

Figure 6: Aided speech recognition in noise scores for self-fit and AUD fit. Mean and standard deviations are shown for 33 participants.



A secondary endpoint measure, subjective sound quality ratings were completed after each field trial with the hearing aids. Participants rated the sound quality of 4 different stimuli using a sliding scale on a tablet while in a sound treated booth. Stimuli consisted of instrumental music, a female talker, a male talker, and a movie trailer. **Figure 7** shows sound quality ratings for self-fit (black bars) and AUD-fit (open bars) conditions. Results showed very similar mean and standard deviation scores when comparing the overall sound quality ratings for the two fitting approaches.

Figure 7: Sound Quality Ratings self-fit and AUD fit. Mean and standard deviations are shown for 33 participants.



Eargo also administered a sound quality satisfaction survey to hearing impaired individuals who have used Eargo devices (hearing aids and the Eargo mobile app) in the field (i.e., real-world situations) for two months or longer. The Eargo app allowed the users to adjust treble, bass, overall volume, and noise reduction settings amongst other

things. Survey participants were asked about their satisfaction with the device's sound quality across a range of situations and environments (including speech perception in various contexts, including in noise, listening to music, watching TV, etc.) following device use in the real world. Data from 255 survey respondents indicate that the device's subjective sound quality was acceptable.

References

[1] Keidser G, Dillon H, Flax T, et al. (2011). The NAL-NL2 prescription procedure. Audiol Research.
[2] Cox R, Alexander G. (1995). The Abbreviated Profile of Hearing Aid Benefit (APHAB). Ear Hear 16: 176-186.
[3] Sabin A, Van Tasell B, Rabinowitz B, Dhar S (2020). Validation of a self-fitting method for over-the-counter hearing aids. Trends in Hearing 24: 2331216519900589.

- USABILITY/HUMAN FACTORS

The usability of the Eargo Self-Fitting Hearing Aid system was evaluated with respect to physical fit (the comfort and fit of the hearing aids) and safety during real-world use, general usability and satisfaction following real-world use, and human factors of Eargo's self-fitting functionality, device labeling, and device handling and maintenance.

Real-World Evaluation of Fit and Comfort

To evaluate the fit, migration, and comfort (FMC) of the Eargo Self-Fitting Hearing Aids, Eargo conducted a long-term, real-world usability study. The scope of testing assessed the fit and comfort characteristics of the hearing aid system (i.e., the hearing aids and charger) in a real-world use setting and was not focused on the system's self-fit capabilities (e.g., app-based self-fitting procedure).

Thirty-three participants with hearing impairment were provisioned with pre-production hearing aids, explained on its functionality and usage, assisted with its fit and eartip style and size selection, and instructed to wear the hearing aids in everyday settings. After at least two weeks of wear time, experimenters contacted participants and collected feedback related to overall fit, migration tendency (unwanted/unintended movement during wear), and level of comfort. Because the study was focused on fit and comfort, participants were not introduced to the companion Eargo mobile app.

All 33 study participants provided feedback regarding the fit and comfort of the hearing aids. Participants provided feedback on the overall FMC characteristics of the Eargo 5 hearing aids following 2 weeks (or longer) of daily wear. The results are shown in **Table 4**.

Table 4: Fit, Migration, Comfort of Eargo 5 Hearing Aids

Question	Response
Describe the fit of the device in your ear.	88% rated “Good” or “Excellent”
On average, how many times per day do the devices move (migrate) out of your ear?	94% rated “Never” or “1-2 times daily”
Do you experience any discomfort while wearing the devices?	94% rated “Mild” or “No Discomfort”

These results demonstrate that most participants found the subject device hearing aid form factor (and the included ear tips) to be acceptable in terms of fit and comfort in real-world use conditions.

Real-World Evaluation of Safety

To evaluate safety of the Eargo Self-Fitting Hearing Aids, Eargo conducted a long-term, real-world usability study. The scope of testing assessed the incidence of device-related adverse events during real-world use of the hearing aid system (i.e., the hearing aids and charger) and was not focused on the system’s self-fit capabilities (e.g., app-based self-fitting procedure).

In the real-world usability study, 31 participants with hearing impairment were provisioned with production-equivalent hearing aids, explained on its functionality and usage, assisted with its fit and eartip style and size selection, and instructed to wear the hearing aids in everyday settings. Participants wore the devices under real-world conditions for at least one month. During this unsupervised real-world device usage period, participants were instructed to report any device-related issues or health-/safety-related concerns to the experimenters immediately if and when such issues occurred. At the end of the study, experimenters made note of any device-related issues that were mentioned, including any issues that carried medical or safety concerns.

The companion Eargo mobile app was not included in these investigations as these studies focused only on the general use of the hearing aids.

Through the end of the observation period (ranging from 41 days to 210 days, depending on the participant), no health-related issues due to device fit or discomfort were observed, and no device failures leading to potential safety issues were observed. These results suggest that the subject device hearing aids are safe for its intended users.

Real-World Evaluation of Satisfaction and Usability

To evaluate general usability and satisfaction with the Eargo Self-Fitting Hearing Aids, Eargo conducted a real-world survey study. The scope of testing assessed the general usability and satisfaction with the devices (including using the companion Eargo mobile app to make adjustments), satisfaction with subjective sound quality during real-world situations, and perceived benefit from using the devices.

A web-based survey was administered to adult subjects with self-reported hearing impairment, who have used Eargo Self-Fitting Hearing Aids for at least two months, and who have completed the Sound Match self-fitting procedure using the companion mobile app.

Responses from 255 subjects meeting the inclusion criteria above demonstrated acceptable usability and satisfaction in all assessed areas. Specifically, system usability pertaining to Sound Match completion, device maintenance and cleaning procedures, satisfaction with subjective sound quality across a variety of real-world situations/environments, usability of and satisfaction with app-based device adjustments, and perceived benefit - all demonstrated acceptable usability and user satisfaction.

Human Factors Validation of Self-Fit Strategy

To assess the overall usability and intuitiveness of the self-fitting approach, Eargo conducted a human factors validation test (summative usability test) of Eargo Self-Fitting Hearing Aids. The scope of testing focused on the human factors associated with various use case scenarios related to self-fitting and was not focused on assessing the accuracy of self-fitting or perceived benefit of the Eargo Self-Fitting Hearing Aids.

The human factors validation of Eargo Self-Fitting Hearing Aids included 16 participants (11 male, 5 female) ranging from 22-95 years in age (mean: 55 years). The sample population was naive to the app-based self-fitting function of the Eargo Self-Fitting Hearing Aids and balanced with respect to perceived mild to moderate hearing impairment (8 with perceived impairment, 8 without).

Participants performed four, hands-on use case scenarios related to the self-fit procedure, each with action-based or knowledge-based tasks embedded within the scenarios. The scenarios assessed the user's experience in completing Sound Match, using the Eargo mobile app to make program and setting changes to the hearing aids, making in-situ program changes to the hearing aids without using the mobile app, and understanding the process of resetting hearing aids back to factory default settings. The specific use cases are described in **Table 5**.

For each use case scenario, one or more critical tasks were identified, such that their incorrect or incomplete performance may result in an improper self-fitting. Three critical tasks were identified for completing Sound Match, two critical tasks for using the mobile

app to make program and setting changes, and one critical task each for making in-situ program changes and reverting the hearing aids back to factory default settings.

During the completion of each use case scenario, experimenters observed and rated whether each task within the scenario was completed successfully, completed with difficulty, completed with assistance, or failed (or unable) to complete (i.e., use error). Participants were instructed to complete each scenario on their own and ask for assistance when they felt it was required. The experimenter did not assist unless asked.

All four use case scenarios met the acceptance criteria of being completed successfully by at least 80% of participants. No use errors (failure or inability to complete) were observed for any tasks within any scenarios.

Table 5: Summary of Self-Fitting Use Case Scenario Results.

Use Case Scenario	Result
Completing Sound Match	PASS
Using mobile app to change programs/settings	PASS
Making in-situ program changes without mobile app	PASS
Reverting settings back to factory defaults	PASS

The use case scenarios related to completing Sound Match, using the mobile app to make program and setting changes, making in-situ program changes without the mobile app, and reverting hearing aids back to factory defaults were all completed with a high rate of success. The results demonstrate that the tasks (including critical tasks) required to complete each use case scenario were easy to complete by naive participants.

Human Factors Validation of Device Labeling and Device Handling/Maintenance

To assess the general usability and self-selection of the Eargo Self-Fitting Hearing Aids in intended use conditions (i.e., "intended for use without the assistance of a hearing care professional."), Eargo conducted a human factors validation test on the device's labeling, self-selection, and handling and maintenance procedures. The scope of testing focused on the human factors associated with use case scenarios related to label understanding, device self-selection, and general device handling and maintenance, completed only with relevant retail-equivalent instructional information, and without any assistance from the experimenters. The scope of this testing was not focused on assessing the accuracy of self-fitting or perceived benefit of the Eargo Self-Fitting Hearing Aids, nor on the general usability of the companion Eargo mobile app.

The human factors validation testing included 24 participants (15 male, 9 female, 1 other) with self-reported hearing impairment (mean HHIE-S: 17.5), ranging from 26-78 years in age (mean: 47 years). The sample population was naive to the Eargo Self-Fitting Hearing Aids.

Participants performed two knowledge-based use case scenarios related to device labeling and four hands-on use case scenarios related to device handling and maintenance using only the relevant retail-equivalent instructional content, without any assistance from the experimenters. The knowledge-based scenarios assessed the user's understanding of device indications, warnings, and cautions, while the task-based scenarios assessed the user's experience in device charging, eartip self-selection, device insertion and removal, device maintenance, and device cleaning. The specific use cases are described in Table 6.

Table 6. Summary of Device Labeling and Handling/Maintenance Use Case Scenario Results.

Use Case Scenario	Result
Understanding of outside the package device labeling (Indications and Warnings)	PASS
Understanding/acknowledgement of inside the package device labeling (Cautions, device use expectations)	PASS
Device charging	PASS
Eartip self-selection, replacement, and device insertion/removal	PASS
Mic cap replacement	PASS
Device cleaning	PASS

For each use case scenario, one or more critical tasks were identified, such that their incorrect or incomplete performance may result in improper device usage. One critical task was identified for understanding device indications and warnings, one critical task for understanding cautions and device use expectations, one critical task for device charging, two critical tasks for eartip selection and device insertion, and one critical task for device cleaning.

During the completion of each use case scenario, experimenters observed and rated whether each task within the scenario was completed successfully, completed with difficulty, completed with assistance, or failed (or unable) to complete. For each scenario, participants were provisioned with the relevant instructions for use information and

instructed to complete each scenario on their own. Given that the objective of the testing was to evaluate device interactions in intended use conditions, a task was considered a failure if the subject needed to ask the experimenter for assistance. All six use case scenarios met the acceptance criteria of being completed successfully and independently by at least 80% of participants.

- SUMMARY

The Eargo Self-Fitting Hearing Aid has the same intended use as the predicate device, the Bose SoundControl™ Hearing Aid (K211008). As with the predicate device, the subject device is a self-fitting air-conduction hearing aid that incorporates wireless technology, intended for over-the-counter sale to individuals 18 years or older with perceived mild to moderate hearing impairment. The subject device has been verified and validated per the same standards and guidelines as the predicate device. Clinical data demonstrate Eargo Self-Fitting Hearing Aid's ability to measure air-conduction hearing thresholds as accurately as audiology standard of care and deliver adequate amplification to meet widely accepted clinical prescription targets for mild to moderate hearing loss. The evidence from the clinical validation study provided strong support for the conclusion that the Eargo self-fitting hearing aid has a reliable self-fitting method and will provide the intended population of adults (with perceived mild to moderate hearing loss) with functional performance that is not inferior to that provided by a professional hearing aid fitting. The findings of this clinical trial are similar to those from the Bose predicate device study (K211008). In addition, the system usability was rated as highly satisfactory.

Additional clinical data demonstrate the effectiveness of Eargo Self-Fitting Hearing Aid's acoustic performance, safety, general usability, user satisfaction, and its comparability to the predicate device. Data related to biocompatibility, electrical safety, electromagnetic compatibility, wireless communication, and electroacoustics support substantial equivalence to the predicate device with respect to safety. Differences in technological characteristics from the predicate device, such as CIC form factor and rechargeability, do not raise different questions of safety or effectiveness.

Taken together, the results from clinical studies, and usability studies demonstrate the effectiveness of the subject device's self-fitting strategy for its intended use, including its app-based measurement of hearing thresholds, ability to deliver appropriate amplification to its intended user, acceptable sound quality, ease of wear and self-fitting process, and safety. Thus, the clinical and non-clinical performance data demonstrate that the Eargo Self-Fitting Hearing Aid is substantially equivalent to the predicate device.