July 13, 2026

Meta Platform Technologies, LLC
Lucas Fernandez
Director
Reality Labs Medical Devices, Health Technologies Team
333 Airport Blvd.
Burlingame, California 94010

Re: K254044
Trade/Device Name: Hearing assist
Regulation Number: 21 CFR 874.3335
Regulation Name: Air-Conduction Hearing Aid Software
Regulatory Class: Class II
Product Code: SCR
Dated: June 10, 2026
Received: June 11, 2026

Dear Lucas Fernandez:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SRINIVAS NANDKUMAR -S

Srinivas Nandkumar, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254044

Please provide the device trade name(s).

Hearing assist

Please provide your Indications for Use below.

Hearing assist is an over-the-counter (OTC), self-fitting software as a medical device (SaMD) hearing aid to be used with compatible wearable electronic products. Hearing assist is intended to compensate for perceived mild to moderate hearing loss for users 18 years of age and older. Hearing assist utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional.

Please select the types of uses (select one or both, as applicable).

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

1. Submitter Information

Submitter:	Meta Platforms Technologies, LLC 333 Airport Boulevard Burlingame, California 94010 Email: rl_mdcompliance@meta.com
Primary Correspondent:	**Lucas Fernandez** Director of Medical Devices | Meta 333 Airport Boulevard Burlingame, California 94010
Secondary Correspondent:	**Elizabeth Khalil** Regulatory Affairs Lead | Meta 333 Airport Boulevard Burlingame, California 94010
Date Prepared:	July 13, 2026

2. Device information

Device Name:	Hearing assist
Common Name:	Air-conduction hearing aid software
Regulation Number:	21 CFR 874.3335
Regulation Name:	Air-conduction hearing aid software
Product Code:	SCR
Regulatory Class:	Class II

3. Predicate Device Information

Device Name:	Apple Hearing Aid Feature (HAF)
510(k) Number:	DEN230081
Manufacturer:	Apple Inc.

The predicate device has not been subject to a design related recall.

4. Device Description

The Meta Hearing assist feature is an air-conduction hearing aid software medical device (SaMD) intended to be used with a smart glasses wearable multi-function hardware platform to compensate for impaired hearing. Hearing assist is comprised of a pair of software modules which operate on two separate required products: (1) Hearing assist Smartphone iOS Application on a compatible iOS phone, and (2) Hearing assist Smart Glasses App software (i.e., firmware) on a compatible wearable electronic computing platform. Refer to Figure 1.

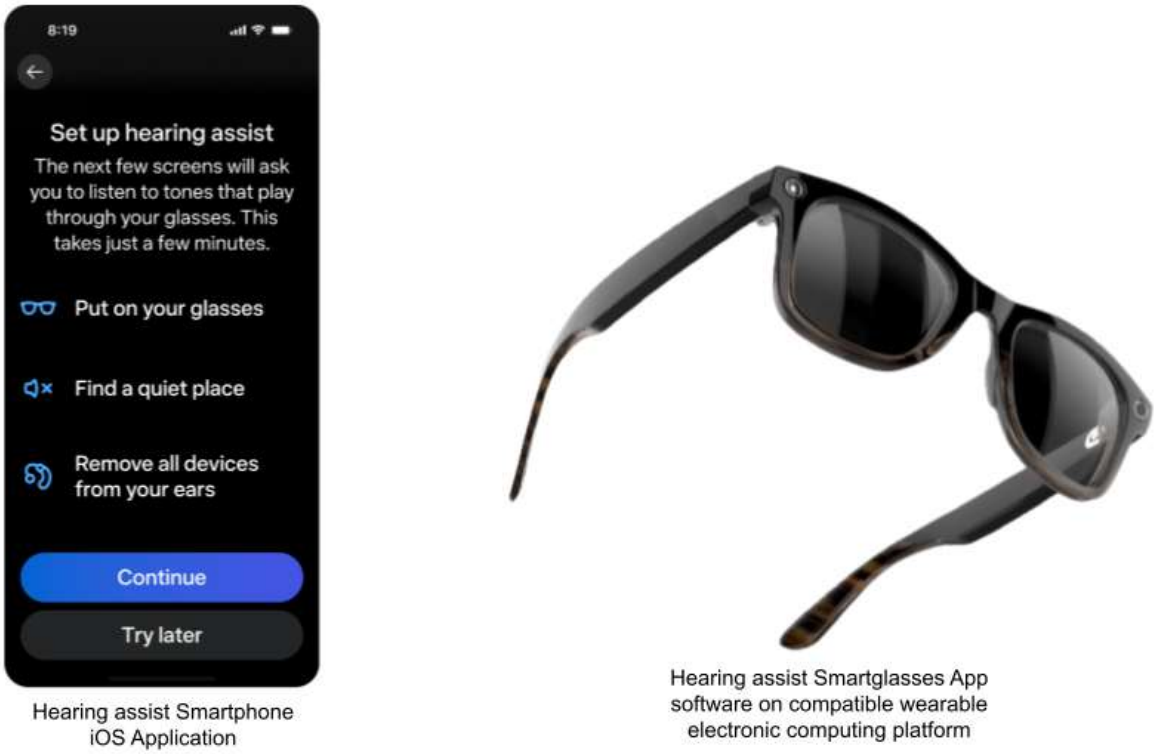

Figure 1: Meta Hearing assist Platform Components

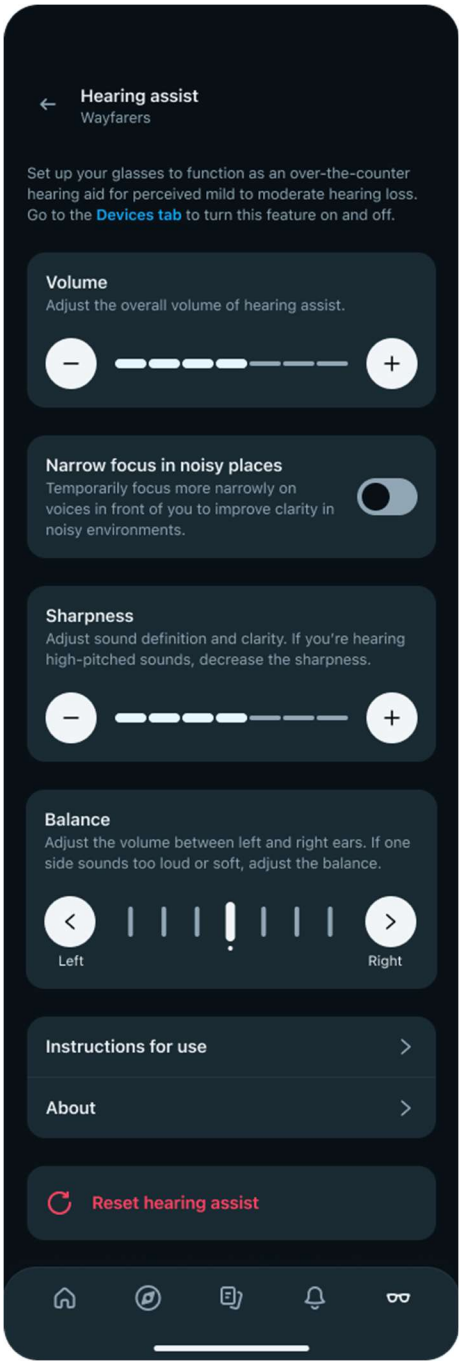

Figure 2: Meta Hearing assist main screen for iOS

Hearing assist is intended for over-the-counter (OTC) use and is self-fit and customized by the user to meet their hearing needs. It is intended for individuals 18 years of age or older with perceived mild to moderate hearing loss.

Users must complete onboarding and self-fitting via the Smartphone app while wearing the glasses in order to create a hearing profile prior to use of the Hearing assist device. The hearing

test/profile generator functionality is integrated into the Hearing assist software modules and is not a standalone application. The hearing profile is a proprietary data format that specifies how real-world sounds should be amplified for each ear. Once users complete self-fitting (i.e. have a hearing profile), they can turn on Hearing assist's real-world sound amplification to compensate for their hearing loss. In addition to onboarding and self-fitting, the Hearing assist Smartphone App contains settings and personalization controls for Hearing assist (Figure 2). Volume and sharpness user controls in the Meta Hearing assist Smartphone app applies adjustments bilaterally (i.e., to both ears simultaneously). These user controls cannot be fine-tuned independently for each ear. However, the effective gain realized in each ear is bounded by per-ear gain limits, ensuring safe amplification in both the better and poorer ear.

The Hearing assist Smart Glasses App is installed and runs within the smart glasses platform. The Hearing assist Smart Glasses App uses the smart glasses platform hardware (such as microphones and loudspeakers) and software (such as audio processing pipelines and control interfaces) features provided by the smart glasses platform to perform device functions such as playing tones during self-fitting, processing incoming environmental sound, and delivering amplified sound based on the user's hearing profile. The Hearing assist Smart Glasses App is also responsible for calculating and storing/persisting the user's hearing profile after the self-fitting process is completed.

5. Indications for Use

Hearing assist is an over-the-counter (OTC), self-fitting software as a medical device (SaMD) hearing aid to be used with compatible wearable electronic products. Hearing assist is intended to compensate for perceived mild to moderate hearing loss for users 18 years of age and older. Hearing assist utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional.

6. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below compares the intended use and the technological characteristics of the subject device and predicate device.

Table 1: Summary of substantial equivalence

	Subject Device	**Predicate Device**	**Comparison**
Trade name	**Meta Hearing assist**	**Apple Hearing Aid Feature (HAF)**	
FDA Number	K254044	DEN 230081	N/A
Product Code	SCR	SCR	Same as predicate
Regulation Number	21 CFR 874.3335	21 CFR 874.3335	Same as predicate
Regulatory Class	II	II	Same as predicate

	Subject Device	Predicate Device	Comparison
Trade name	**Meta Hearing assist**	**Apple Hearing Aid Feature (HAF)**	
Patient Population	Individuals 18 years of age or older with perceived mild to moderate hearing impairment.	Individuals 18 years of age or older with perceived mild to moderate hearing impairment.	Same as predicate
Indications for Use	Hearing assist is an over-the-counter (OTC), self-fitting software as a medical device (SaMD) hearing aid to be used with compatible wearable electronic products. Hearing assist is intended to compensate for perceived mild to moderate hearing loss for users 18 years of age and older. Hearing assist utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional.	The Hearing Aid Feature is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The Hearing Aid Feature utilizes a self-fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.	The indications for the subject and predicate devices are the same; both devices are intended for similar patient populations. The compatible wearable electronic devices are different for the subject and predicate devices, i.e. smart glasses vs ear buds platforms.

	Subject Device	Predicate Device	Comparison
Trade name	**Meta Hearing assist**	**Apple Hearing Aid Feature (HAF)**	
Wearable Platform	Hearing assist is housed in the compatible Smart Glasses which is a combination of a class 1 medical device for vision correction and general computing platform for features such as cameras for picture taking and mics/speakers for audio. Hearing assist uses the general purpose platform hardware and software features to perform medical device functions during the user's self-fit journey and for delivering amplified sound based on the user's hearing profile.	The HAF software is housed in the Apple AirPods Pro 2, a consumer electronic earbud. The amplified sound is delivered via an ear-tip situated inside the ear canal.	Different Both the subject and predicate device use general computing platforms for their device functions. The Smart Glasses deliver the air conducted signal without the device obstructing the ear canal, whereas the predicate device uses a compatible hardware that resides within the concha and ear canal. Any technology differences do not raise any new safety or effectiveness questions. Performance testing, including bench and clinical, evaluated these differences in technology and the results support substantial equivalence. A glasses form factor with external speaker and mic placement has been previously cleared by FDA under K243150 (Nuance) under the SCR product code.

	Subject Device	Predicate Device	Comparison
Trade name	**Meta Hearing assist**	**Apple Hearing Aid Feature (HAF)**	
Fitting Method	The Hearing assist Smart Phone application guides the user through the initial onboarding and self-fitting process, providing step-by-step instructions to guide the users. There are three types of adjustments (volume, sharpness, balance) that the user can make to optimize their hearing preferences. The user is able to adjust the fine-tuning settings anytime in the Smart Phone application.	The Apple HAF requires the user to select a hearing test result from the Health app on the iOS device. Once the HAF onboarding is completed, then fine-tuning becomes available to the user. There are three types of adjustments (Amplification, Tone and Balance) that the user can optimize for their hearing preferences. The user is able to adjust the fine-tuning settings anytime on a compatible iPhone, iPad, MacBook or Apple Watch.	Similar to predicate. Both subject and predicate devices use a self-fitting strategy. Both devices are intended for OTC use and do not require the assistance of a professional. The subject device was tested and verified to meet the amplification needs for the intended users in both clinical and non-clinical testing.
Input signal compression	Wide dynamic range compression	Wide dynamic range compression	Same as predicate
Microphones	Multiple Microphone System in the glasses can be configured by the user in standard (all-around) or focus (frontal) mode.	Microphones in AirPods can be configured by User in omni-directional and directional mode.	Similar to predicate
Battery technology	Rechargeable Li-ion battery	Rechargeable Li-ion battery	Same technology
Battery lifetime	Hearing assist is designed to last at least 3 hours of continuous use on fully charged Smart Glasses. The companion charging case provides up to 32 hours of charging for glasses.	~4-6 hours on single charge and a companion charging case	Similar to predicate. Performance testing on subject device support substantial equivalence including 800.30(e)

	Subject Device	Predicate Device	Comparison
Trade name	**Meta Hearing assist**	**Apple Hearing Aid Feature (HAF)**	
Active noise reduction	Included	Included	Similar to predicate
Mobile App	Mobile application on a compatible iOS operating platform.	Mobile application on a compatible iOS operating platform.	Similar to predicate
Remote firmware updates	Remote firmware updates via mobile application.	Remote firmware updates via mobile application.	Similar to predicate
Latency clause	Device Latency: 9.25 msec	Median Latency: 3.15 msec	Subject device meets 21 CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence.
Frequency response	232 Hz to 7809 Hz	100 - 10,000 Hz	Similar to predicate Both the subject and predicate device meet the requirements of 21 CFR 800.30 (e) for Frequency Response Bandwidth.
Self generated noise value	Max Self-Generated Noise: 25.2dBA	Max Self-Generated Noise: 28.2 dBA	The subject device meets 21 CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence.
Harmonic distortion	Less than or equal to 2%	Less than or equal to 1%	The subject device meets 21 CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence.
Maximum output value (Output Sound Pressure Level 90) (OSPL90)	Max OSPL90: 108.6 dB SPL	Max OSPL90: 105.93 dB SPL	The subject device meets 21 CFR 800.30 requirements. Performance testing evaluated these differences in technology and the results support substantial equivalence.

7. Summary of Non-Clinical Performance Testing

Hearing assist was tested for conformity to the following FDA recognized consensus standards applicable to the OTC air conduction hearing aids for the device's intended use.

Electro-Acoustics	● ANSI S3.22: Specification of Hearing Aid Characteristics ● ANSI/CTA-2051: Electroacoustics-Hearing aids-Measurement of electroacoustic characteristics
Software and labeling	● IEC 62304 Ed 1.1 (2015) Software life cycle ● 21 CFR 800.30 (2022 Final Rule)
Electrical Safety and EMC	● IEC 60601-1:2005 + A1:2012 + A2:2020 ● IEC 60601-2-66:2019 ● IEC 60601-1-11:2015 + A1:2020 + A2:2022 ● IEC 60601-1-2, AMDI:2020; Part 1-2

Testing was also performed to show conformance to the Special Controls for air-conduction hearing aid software, as specified in the De Novo classification order for software-only hearing aid features (DEN230081). Hearing assist passed all the relevant non-clinical performance tests with representative, compatible computing platform hardware (Smart Glasses) and was verified that the amplified acoustic signal output by the hardware platform is calibrated. Software verification and validation, testing against established standards for electrical safety, EMC, and battery safety were conducted using representative, compatible hardware (Smart Glasses) platforms to verify the amplified acoustic signal output. Supplementary electrical safety and EMC testing was completed to demonstrate compliance to the medical device standards listed above.

A bench performance comparison of gain between the subject and predicate devices was performed to further support substantial equivalence. Frequency-specific real-ear insertion gain (REIG) was characterized on a head and torso simulator (HATS) using a speech stimulus at a conversational input level, evaluated across four audiometric profiles representing mild through moderate hearing loss. The subject device achieved gains closely aligned with NAL-NL2 prescriptive targets and provided comparable amplification to the predicate.

Human Factors and Usability Testing

Per Special Control 3 for an OTC medical device intended to be used without the support of a hearing healthcare professional, human factors and usability validation studies were conducted, in compliance with IEC 62366-1:2015. Test results demonstrated that end-users can correctly and safely perform all critical tasks for using the Hearing assist software medical device (SaMD) within a simulated use environment. This testing assessed the effectiveness of the user interface and supporting instructional materials, ensuring usability, minimizing the risk of user error, and confirming that users are able to navigate the system, understand instructions, and achieve successful device setup and routine operation. Representative users were able to complete all tasks without critical errors, and all defined acceptance criteria were met.

Clinical Data

Hearing assist was validated in a clinical investigation involving 142 subjects aged 18 years or older with mild to moderate hearing impairment, or perceived hearing difficulties with normal hearing thresholds. Subjects reflected the intended OTC user population and were enrolled based upon an audiological assessment of hearing thresholds defined by the four-frequency pure tone average (4PTA). The enrolled subjects were distributed across each of the following categories: No Impairment/Perceived Hearing Loss (4PTA: 15-25 dB HL), Mild Hearing Loss (4PTA: 26-40 dB HL), and Moderate Hearing Loss (4PTA: 41-60 dB HL). Subjects were also enrolled based on specific age and sex targets, representative of the intended patient population.

The study was performed at three clinical sites across the United States and conducted over two phases. Phase one was conducted in a clinical lab-based setting where hearing aids were fit and clinical assessments performed. The second phase was conducted in the participants' home and community over a 14-day period, where they could freely use their hearing aid device in their own natural listening environments. The study compared two groups: a self-fit (SF) group where subjects independently set up the hearing aid device, and a pro-fit (PF) group where the hearing aid device was set up and fitted by a licensed hearing care professional. Study success was determined by pre-specified primary and secondary endpoints. The primary endpoint was a measure of clinical effectiveness, assessed by the mean group-total score of the International Outcome Inventory for Hearing Aids (IOI-HA) survey. This was evaluated after 14 days of field use. The secondary endpoint was a measure of objective clinical benefit, determined by the average Speech-in-Noise performance using the Quick Speech-in-Noise (QuickSIN) test. All tests were designed to determine non-inferiority of clinical benefit between the SF and PF fitting methods.

The clinical investigation met all predefined objectives. For the primary endpoint, subjects in the SF group were able to achieve the same clinical benefit, compared with subjects who had their settings tuned by a licensed hearing care professional. The mean IOI-HA total scores for the SF and PF cohorts were 25.77 (SD = 4.28) and 26.81 (SD = 3.56), respectively. The mean difference (defined as SF – PF) between the two cohorts was -1.04 (SD = 3.93), with the 95% confidence interval of the mean difference being (-2.28, 0.24) and the p-value for the non-inferiority test being 0.004. Thus, the null hypothesis was rejected, and the SF group was found to be non-inferior to the PF group. Subgroup analyses indicated that the IOI-HA scores were consistent for both the SF and PF groups across hearing classification, age, sex, and race.

The secondary endpoint was also met. The mean SNR Loss scores for the SF and PF cohorts were 4.4 dB (SD = 5.7) and 4.2 dB (SD = 5.9), respectively. The mean difference (defined as PF – SF) between the two cohorts was -0.2 dB (SD = 2.4), with the 95% confidence interval of the mean difference being (-0.5, 0.3) and the p-value for the non-inferiority test being less than 0.001. Thus, the null hypothesis was rejected, and the SF group was found to be non-inferior to the PF group. Subgroup analyses indicated that the mean SNR Loss scores were consistent for both the SF and PF groups across hearing classification, age, sex, and race.

Additional objective measures were also made related to Speech-in-Noise and Real Ear Insertion Gain. A within-participant assessment of speech-in-noise performance showed an average signal-to-noise (SNR) benefit of 4.8 dB (SD = 5.3) with SF. This implies participants could understand speech more easily in noisy environments when using Hearing assist compared to without, reflecting an improvement in their ability to hear when background sounds

are present. Real Ear Measures (REM) were also collected to assess objective differences in amplification between the SF and PF groups. REM results confirmed equivalent insertion gains across all speech input levels (50, 65, 75 dB SPL), consistent with non-inferior IOI-HA and SNR Loss outcomes.

During the course of the clinical investigation, all adverse events (AEs) were systematically recorded and analyzed. There were no unanticipated adverse device effects (UADE) or serious adverse device effects (SADE) reported. There were 6 adverse device effects (ADEs) reported by 5 out of 142 participants. Headache was the most commonly reported issue with 5 reports (2.5 events per 1000 observed days). There was 1 report of tiredness and fatigue (0.5 events per 1000 observed days). The reported issues are consistent with the expected safety profile of a Non-Significant Risk (NSR) device, as they do not pose a significant risk to the health, safety, or welfare of study subjects. Headache and fatigue are anticipated side effects for individuals using hearing aids, especially during the initial periods of use while they acclimate to a new device. Importantly, these side effects were reported to be mild and transient in nature, with all subjects fully recovering without any intervention. No subjects withdrew from the study as a result of these effects.

The study had a total of four serious adverse events (SAEs) experienced by 2 out of 142 participants, unrelated to the study device or procedures. One subject experienced a fall with injury and the other had a cardiac event. Both required hospitalization.

There was 1 out of 142 participants who withdrew from the study prior to study completion. Also, there were 5 important protocol deviations reported (4 participants with assessments outside the visit window and 1 participant who was not compliant with the device usage requirement). Robust sensitivity analyses demonstrate that these issues did not impact the study's findings. Overall, the clinical investigation provides reasonable assurance of the safety and effectiveness of Hearing assist. The findings generated from this clinical investigation provide substantial scientific evidence and reasonable assurance that the Hearing assist hearing aid is at least as safe and effective as the legally marketed predicate device (Apple HAF, DEN230081).

8. Predetermined Change Control Plan

Hearing assist contains a Predetermined Change Control Plan (PCCP) in accordance with 515(c) of the Federal Food, Drug and Cosmetic Act. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field. All algorithm modifications will be locked and validated prior to release of the software to the field.

The PCCP is for the addition of an Android mobile platform for the Hearing assist Smartphone App in addition to the iOS platform. The PCCP specifies verification and validation activities in place to implement the Android mobile platform in a controlled manner such that the device remains as safe and effective as the predicate device. The table below outlines the planned testing for implementing the Android mobile platform.

Planned Change	Requirements	Test Method
Launch of Android mobile platform for the Hearing assist smartphone application	● No change to input type ● No change to output type ● No changes to any other modules of the Hearing assist feature ● No change to the intended use ● Can be fully verified through requirements specified in the protocol ● Cybersecurity requirements for Android mobile platform	Meet the functional and performance requirements as outlined in product requirements. Relevant/applicable cybersecurity testing will be conducted to support the launch of the Android mobile platform.

9. Conclusion

The results of the performance testing described above demonstrate that the Hearing assist is as safe and effective as the predicate device (Apple HAF, DEN230081) and supports a determination of substantial equivalence.