August 4, 2022

MDHearingAid
Doug Breaker
CEO
150 N Michigan Avenue Suite 400
Chicago, Illinois 60601

Re: K220303
Trade/Device Name: MDHearing Smart Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QDD
Dated: July 1, 2022
Received: July 5, 2022

Dear Doug Breaker:

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,

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)*
K220303

Device Name
MDHearing Smart Hearing Aid

Indications for Use *(Describe)*
The MDHearing Smart Hearing Aids are self-fitting air-conduction hearing aids, 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.

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary – K220303

I. SUBMITTER

MDHearingAid
150 N. Michigan Avenue
Suite 400
Chicago, IL 60601

Contact Person: Doug Breaker
Phone: 844-944-3277
Fax: 312-598-1068

Date Prepared: June 29, 2022

II. SUBJECT DEVICE

Trade / Device Name: MDHearing Smart Hearing Aid
Common or Usual Name: Self-fitting air-conduction hearing aid
Classification Name: Self-fitting air-conduction hearing aid
Regulation Number: 21 CFR 874.3325
Product Code: QDD
Regulatory Class: Class II
Panel: Ear, Nose, and Throat Devices

III. PREDICATE DEVICE

Bose® Hearing Aid (DEN180026)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The MDHearing Smart Hearing Aid is a self-fitting wireless air conduction hearing aid system consisting of the Intricon Lumen 200B hardware and software and the MDHearing mobile application, which is an “app” compatible only with MDHearing devices of a Smart Hearing Aid product line, designed to interface with a user’s compatible smartphone or tablet to personalize and manipulate the device and its settings. The wireless hearing aid (**Figure 1**) incorporates microphones and a receiver encased in the behind-the-ear (BTE) hearing aid body, delivering amplified sound to the ear via standard thin tubing coupled to an earpiece for audio input into the ear. The hearing aid can be controlled wirelessly via Bluetooth Low Energy® using the MDHearing app or manually with on-device push buttons for changing volume and programs. The controls accessible through the MDHearing app and on the hearing aids are used to

configure parameters, settings, and listening modes of the devices. The MDHearing Smart Hearing Aid is powered by a standard disposable size 312 zinc-air hearing aid battery.

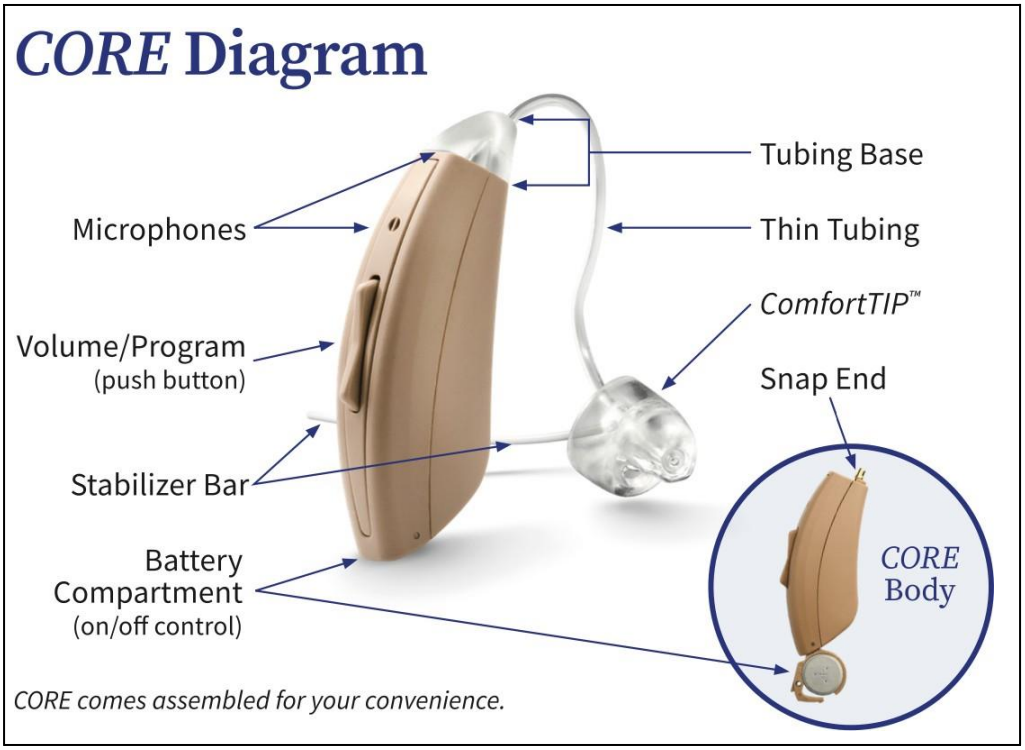


Figure 1. Diagram of the MDHearingAid® *CORE,* a wireless hearing aid of the MDHearing Smart product line, compatible with the MDHearing app and utilizing the Intricon Lumen 200B platform, representative of the subject device.

The MDHearing mobile application (MDHearing app) is designed to function with a user's compatible personal device, providing an interface for remote, wireless control and configuration of MDHearing Smart Hearing Aids. The app is available free for download on iOS or Android based systems. The MDHearing app is compatible only with MDHearing devices of the Smart Hearing Aid product line. It cannot be used to pair a device with any other brand of hearing aid or with hearing aids that are not part of the Smart product line. The MDHearing app cannot be used independently of MDHearing Smart Hearing Aids.

The MDHearing app allows the user to program the MDHearing Smart Hearing Aid through "self-fitting" strategies by changing various basic functions such as programs and volume, as well as more advanced settings including noise reduction, microphone directionality, and bass, treble, and mid frequency (or Equalizer) settings. Some of these Advanced Settings can only be adjusted after the user completes a personalization process, resulting in a personal profile, or an approximation of hearing sensitivity upon which the hearing aids are fit using the NAL-NL2 fitting formula. The validated NAL-NL2 fitting formula aims to maximize speech intelligibility while maintaining comfortable overall loudness, and it is widely used by hearing care professionals to fit individuals with mild to moderate hearing loss.

V. INTENDED USE / INDICATIONS FOR USE

The MDHearing Smart Hearing Aids are self-fitting air-conduction hearing aids, 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.

VI. LABELING

Self-Selection Labeling has been included in the MDHearing Smart Hearing Aid User Manual to mitigate the risk of improper self-selection. Summarized, it addresses the following:

- Identifying situations in which the MDHearing Smart Hearing Aid may help users hear better.
- Identifying situations in which the MDHearing Smart Hearing Aid may not be right for users.
- Identifying criteria that indicate users should see a hearing professional.
- Informing users that the MDHearing Smart Hearing Aid will not restore normal hearing.
- Informing users that it is good health practice to have hearing loss evaluated by a licensed healthcare professional.

VII. SPECIAL CONTROLS

The MDHearing Smart Hearing Aid conforms to the special controls stated in 21 CFR 874.3325. These requirements were satisfied through the following:

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

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

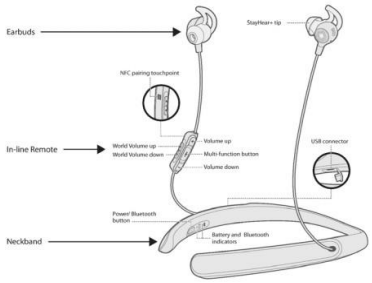
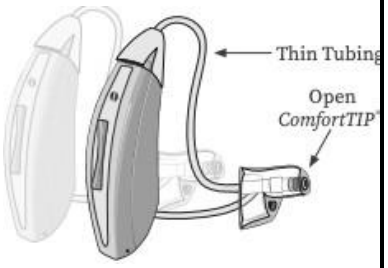
Both the subject (MDHearing Smart Hearing Aid) and the predicate (Bose® Hearing Aid – DEN180026) devices are self-fit, direct-to-consumer hearing aids indicated for individuals 18 and older with perceived mild to moderate hearing impairment. The same fundamental technology is present in both hearing aids to allow the user to control and customize the device to the user's hearing needs.

The key similarities and differences between the predicate device and the subject device with respect to the technological characteristics are summarized in the table below. Any differences in technological characteristics between the subject and predicate device have been addressed

through testing to a known performance standard or by showing equivalency in terms of function. Therefore, these differences are not significant and do not raise additional questions of safety or effectiveness for the subject device.

Key Similarities and Differences between the Bose® Hearing Aid (Predicate Device) and the MDHearing Smart Hearing Aid (Subject Device)

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
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.	The MDHearing Smart Hearing Aids are self-fitting air-conduction hearing aids, 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 and intended users are the same.
Technology	Wireless, self-fitting air-conduction hearing aid	Wireless, self-fitting air-conduction hearing aid	Same

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
Housing	Hearing aid neckband housing that connects to both the left and right ear units with user controls on right earbud wire 	Traditional behind-the-ear (BTE) form factor 	Although the subject device hearing aid housing is wireless and BTE instead of a neckband with wired earbuds, the difference in housing does not raise different questions of safety or effectiveness. Non-clinical and clinical performance testing and validation data, including usability and safety testing, support substantial equivalence.
Wireless communication	Wireless communication with handheld device via Bluetooth	Wireless communication with handheld device via Bluetooth	Same
Wireless control functions via mobile application	-Volume control -Modes (everywhere, front, focused) -Tone correction -Left/Right balance	-Volume control (can adjust overall or R/L individually) -Programs (“Automatic”, “Quiet”, “Conversation”, “Restaurant”) -Equalizer for Low-, Mid-, and High-tones -Noise reduction -Directionality	The additional wireless control functions supported for the subject device do not raise different questions of safety or effectiveness. Non-clinical and clinical performance testing and validation data, including usability and safety testing, support substantial equivalence.

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
Device control	On-Device user controls: - Volume up/down microphone - Volume up/down streaming - Power on/off button - Bluetooth pairing button	On-Device user controls: -Volume up/down -Program up/down -Power on/off (via hearing aid battery door closed or open)	Sound adjustment controls are similar. Powering off/on and Bluetooth pairing mode for the subject device are controlled by opening/closing battery door. The subject device does not support streaming, so the absence of those controls, and the different means of engaging Bluetooth and turning the device on/off, do not raise different questions of safety or effectiveness. Non-clinical and clinical performance testing and validation data, including usability and safety testing, support substantial equivalence.
Mobile App	Mobile application, on handheld device (iOS or Android) used to configure parameters, settings, and listening modes	Mobile application, on handheld device (iOS or Android) used to configure parameters, settings, and listening modes	Same
Battery	Single cell rechargeable 3.7V/270mAh li-ion battery inside neckband	Replaceable, disposable, 1.3Vdc zinc-air hearing aid battery (size 312)	Other legally marketed hearing aids (including those exempt from 510(k) fitted by hearing care professionals)

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
			also utilize disposable zinc-air size 312 hearing aid batteries. As such, the difference in power source does not raise different questions of safety or effectiveness. Non-clinical and clinical performance testing and validation data, including usability and safety testing, support substantial equivalence.
Microphones	Microphones in earbud may, during use, be configured by the user in omnidirectional or directional modes.	Microphones on hearing aid body may, during use, be configured by the user in omnidirectional or directional modes.	Both the subject device and the predicate device allow for omnidirectional and speech focus options. The subject device supports an adaptive directional mode that allows the hearing aids to determine the most suitable directionality for the microphones for the given environment. The added automatic selection of directionality does not raise different questions of safety or

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
			effectiveness.
Compression	12 channel wide band dynamic range compression	8 channel wide band dynamic range compression	The difference in the number of channels is inconsequential for achieving adequate spectral tilt, with both subject and predicate devices having 12 gain adjustment bands, and this does not raise different questions of safety or effectiveness. Data from a clinical validation study support substantial equivalence.
Noise reduction	Active noise reduction, steady state noise reduction, impulse noise control	12-channel layered noise reduction	While differences in the implementation of noise reduction exist, these do not raise different questions of safety or effectiveness. Non-clinical and clinical performance testing and validation data support substantial equivalence.
Feedback cancellation	Feedback canceller	Adaptive feedback cancellation	Same
Self-fitting method	Loudness and Fine-Tuning.	Apply personalized gain	Instead of a proprietary

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
	Utilizes a proprietary fitting algorithm.	settings based on user input and fine-tuning. Utilizes NAL-NL2 fitting algorithm.	algorithm as used by the predicate device, subject device uses the validated NAL-NL2 fitting algorithm, widely used by hearing care professionals to fit persons with mild to moderate hearing loss. Legally marketed hearing aids exempt from 510(k) also embed the NAL-NL2 fitting algorithm, but these exempt hearing aids are fitted by hearing care professionals. As such the difference in fitting strategy does not raise different questions of safety or effectiveness. Data from a clinical validation study support substantial equivalence.
Remote firmware update	Unknown	Remote firmware update via cloud-based solutions with the MDHearing app	Remote firmware update allows MDHearing to maintain and improve Smart hearing aids and strengthen cybersecurity as new mobile operating systems are released. This is assessed as part of the cybersecurity

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
			risk assessment, and this feature does not raise different questions of safety or effectiveness.
Wireless coexistence	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.	The MDHearing Smart (Intricon Lumen200B) Hearing Aid uses the same standard 2.4GHz Classic Bluetooth and Bluetooth Low Energy (BLE) standards as the predicate to communicate between the hearing aid and the user's Bluetooth enabled device. Wireless coexistence testing is not required per AAMI TIR 69.	Same
Electroacoustic parameters (special control 2)	Maximum output limits, distortion levels, self-generated noise levels, latency, full on gain, frequency response, and other parameters as required per 21 CFR 874.3325(b)(2) demonstrated to perform to specifications of ANSI S3.22:2014 and ANSI CTA 2051:2017 standards.	Maximum output limits, distortion levels, self-generated noise levels, latency, full on gain, frequency response, and other parameters as required per 21 CFR 874.3325(b)(2) demonstrated to perform to specifications of ANSI S3.22:2014 and ANSI CTA 2051:2017 standards.	Same See *Non-Clinical Performance Testing* summary ANSI comparison table.

Characteristic	Predicate Device: Bose Hearing Aid (DEN180026)	Subject Device: MDHearing Smart Hearing Aid	Discussion
Exposure to nonionizing radiation (special control 5i)	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.	The equipment operates in the ISM 2.4 GHz band (2.40 – 2.4835 GHz), using the Bluetooth® SMART protocol, and the maximum RF Power transmitted in that band is -10.1 dBm EIRP	Same

While the proposed predicate and subject device are not identical, the technological characteristics are similar, and the technological differences between the predicate device and the subject device do not raise different questions of safety and effectiveness. The table above identifies each of the key technological differences between the MDHearing Smart Hearing Aid and the predicate device as well as the testing performed for each of these differences to demonstrate substantial equivalence. The non-clinical (including usability) and clinical performance testing demonstrate substantially equivalent safety and effectiveness of the MDHearing Smart Hearing Aid as compared to the predicate device.

IX. CLINICAL PERFORMANCE TESTING

Study Design

The clinical study of the MDHearing Smart Hearing Aids and app was a single site, randomized clinical validation study comparing fitting outcomes between individuals using the hearing aids as self-fit versus those fit with the same device by a professional according to audiologic standards of care in a clinical setting. Participants were randomized 1:1 into the two fitting strategies and completed a 1-month field trial in either the “Professional-Fit” group or a “Self-Fit” group. Various performance factors and hearing aid outcomes are examined, including subjective and objective hearing aid benefit with the self-fit MDHearing Smart Hearing Aid versus professional-fit of the same device, appropriateness of amplification as assessed via probe-microphone (real ear) verification measures, and safety data. Reliability and validity of the functionality of the MDHearing app for self-fitting and fine-tuning of the hearing aids was also evaluated.

Subject Demographics

Sixty-four adults aged 18 years or older with sensorineural hearing loss ranging from mild to moderate degree completed this study. **Table 1a** below provides information on the total study population, and **Table 1b** provides information on subject demographics by group (“Self-Fit” / “Professional-Fit”) of the study.

Table 1a. Study Population Summary

Characteristic	N / Total (%)
Age	
18 to 39 years of age	5 / 64 (8%)
40 to 49 years of age	8 / 64 (13%)
50 to 59 years of age	13 / 64 (19%)
60 to 69 years of age	22 / 64 (35%)
60 to 79 years of age	16 / 64 (25%)
Sex	
Female	36 / 64 (57%)
Male	28 / 64 (43%)
Hearing Loss Degree	
Mild	15 / 64 (24%)
Mild to Moderate	49 / 64 (76%)
Hearing Aid Use	
Experienced	40 / 64 (63%)
New	24 / 64 (27%)

Characteristic	N / Total (%)
Technology Use Level* (as reported by subject)	
Low (1-4)	6 / 64 (9%)
Mid (5-7)	24 / 64 (38%)
High (8-10)	34 / 64 (53%)

*Participants were asked to self-rank from 1 to 10 (1: not comfortable at all; 10: very comfortable) their comfort level with technology of electronic devices (e.g., smartphones).

Table 1b. Subject Demographics by Group

Demographic Category	All Subjects	
	Self-Fit	Professional-Fit
Sample Size	32	32
4 Frequency PTA* (dB HL) (mean, s.d.)	29.8, 14.2	35.2, 14.8
Mild Hearing Loss (# of subjects)	9	6
Mild to Moderate Hearing Loss (# of subjects)	23	26
Experienced Hearing Aid Users (# of subjects)	19	21
New Hearing Aid Users (# of subjects)	13	11
Tech. Level (mean, s.d.)	7.8, 1.8	6.8, 2.7
Age (Years) (mean, min-max)	58, 31-76	62, 31-79
Sex (Female, Male)	17, 15	19, 13

* Thresholds measured at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz

Study Procedures

At the first study visit, prior to randomization to groups, all participants completed an assessment of self-fitting reliability to evaluate the performance consistency (or reliability) and validity of the self-fitting and user-controlled adjustments made to hearing aid settings via the MDHearing app. Having completed the personalization process using the MDHearing app and wearing the hearing aids, participants then listened to a recorded speech passage at their most comfortable loudness level (MCL) and were asked to adjust their hearing aids for listening comfort. Probe-microphone (real ear) measures of hearing aid output were completed after each of three iterations of this procedure to evaluate successive gain measurements for stability, and to compare average user-selected gain in the procedure to professionally selected target levels.

After the laboratory reliability measures were completed, all participants were issued a new pair of MDHearing Smart Hearing Aids and underwent initial fitting of the devices either by a clinician programming (professional-fit) or by completing the personalization process using the MDHearing app (self-fit). The baseline visits also included, for all participants, unaided speech-in-noise recognition testing (soundfield Quick Speech in Noise [QuickSIN] test) and completion of pre-fitting (unaided) sections of the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the 12-item short form of the Speech, Spatial and Qualities of Hearing scale (SSQ12).

After one month of field use, participants completed outcome assessments including aided sections of the APHAB, post-fitting "Benefit" version of the SSQ12, and aided QuickSIN testing; a user satisfaction questionnaire was administered for the self-fit group only at the final visit. The professional group had an interim visit for hearing aid reprogramming and fine tuning, if needed, as well as routine hearing aid counseling 2 weeks after baseline intake. Self-fit participants did not have an interim visit with a professional during their field trial.

Study Results

Primary Test Metrics

The primary metric for clinical performance testing was user-reported (subjective) aided benefit achieved after the field trial of the MDHearing Smart Hearing Aids as assessed using two standard questionnaires (APHAB and SSQ12).

The mean scores and distributions of the reported benefit scores were found to be comparable between the self-fit and professional-fit groups, for the two subjective outcome measures (APHAB and SSQ12 benefit scores) (**Figure 2a**).

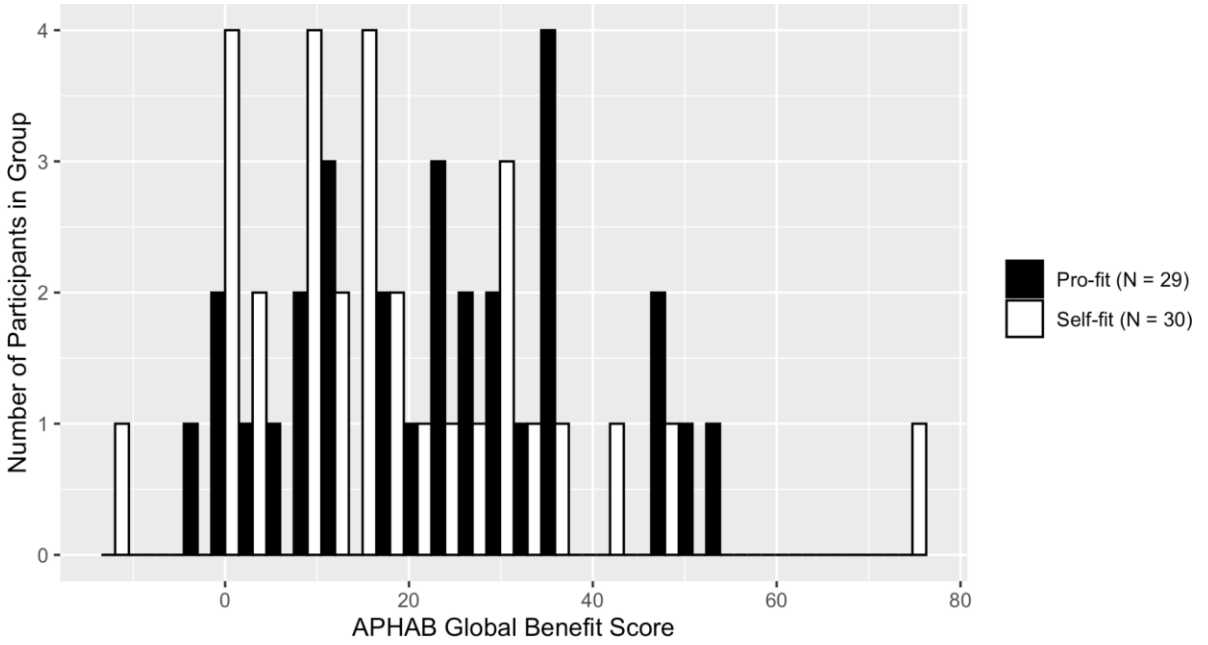


Figure 2a. Distribution of APHAB Global Benefit scores for the professional-fit (black) and self-fit (white) groups.

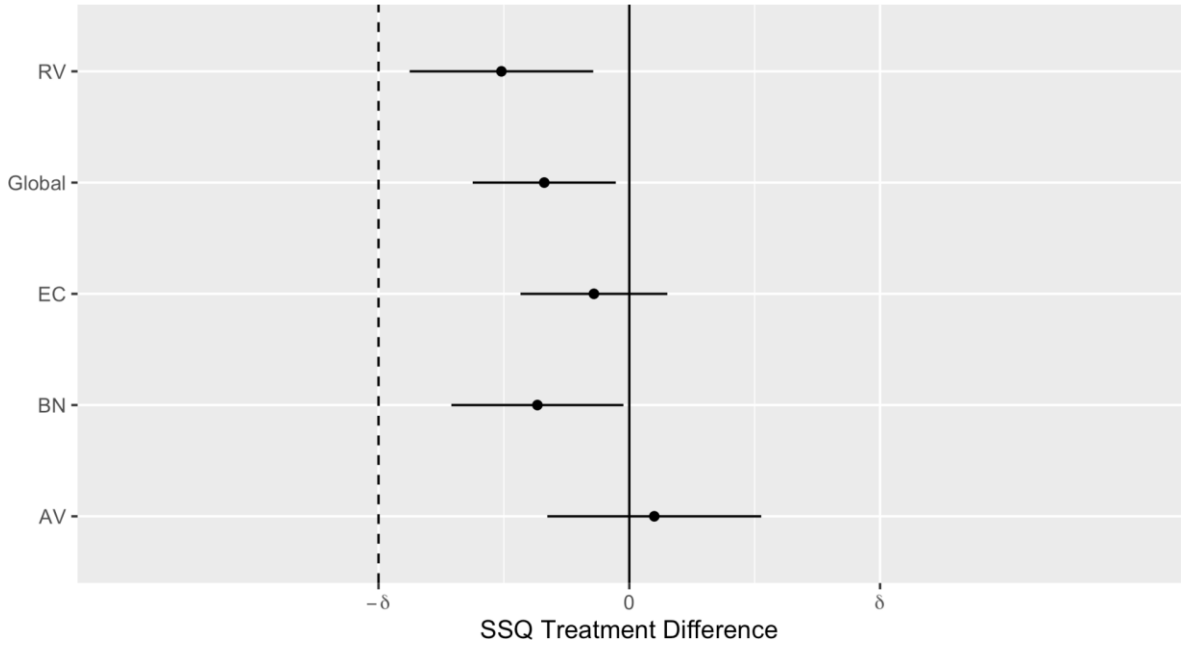


Figure 2b. 95% confidence interval on the difference between self-fit and pro-fit group means for the APHAB. The dashed vertical line shows the non-inferiority margin. If the 95% confidence interval were to extend beyond this boundary, the self-fit scores would be considered inferior to the pro-fit scores on this measure.

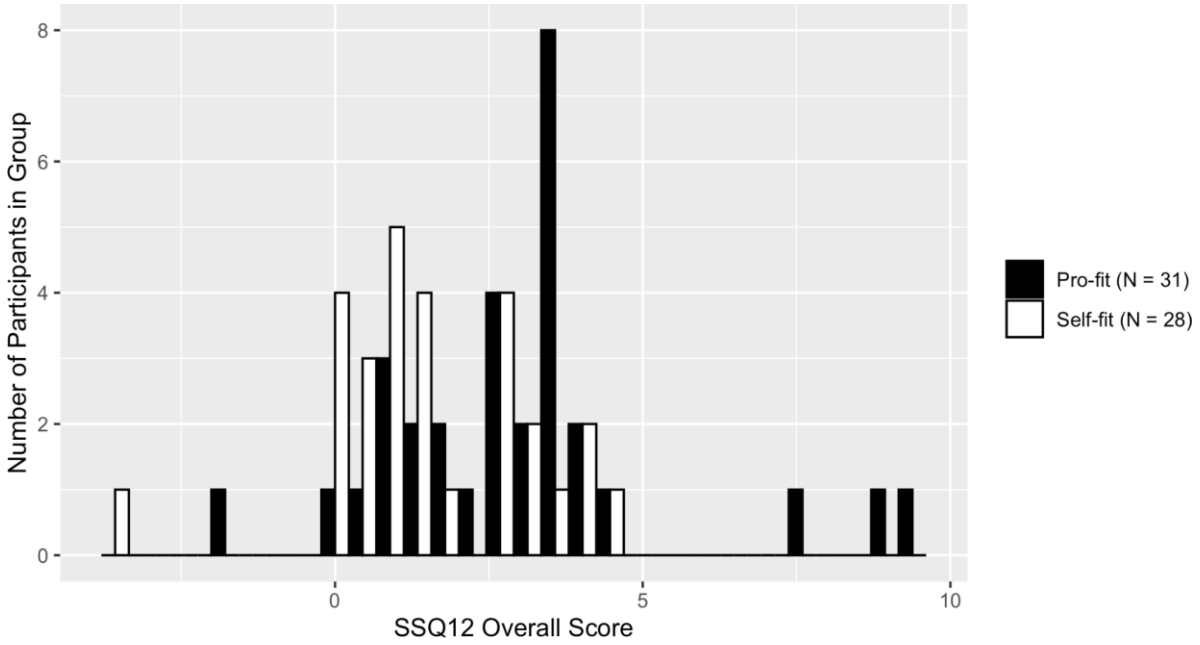


Figure 2c. Distribution of SSQ12 benefit scores for the professional-fit (black) and self-fit (white) groups.

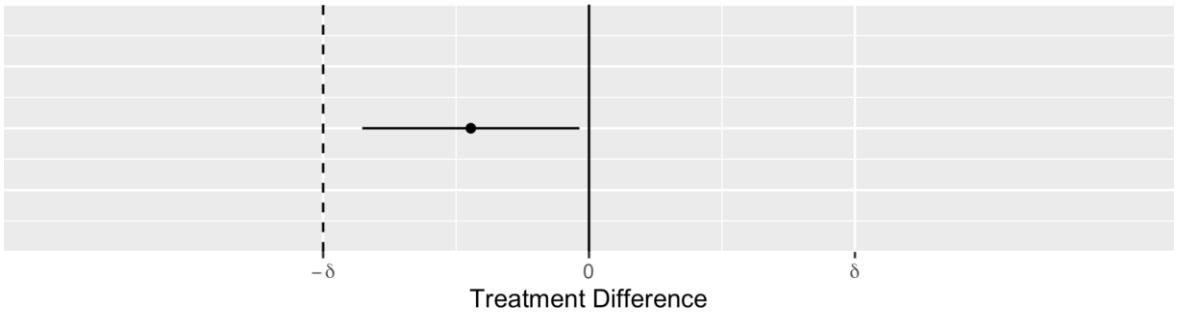


Figure 2c. 95% confidence interval on the difference between self-fit and pro-fit group means for the SSQ12. The dashed vertical line shows the non-inferiority margin.

Secondary Test Metrics and Other Effectiveness Measures:

Speech-In-Noise Recognition

There was no difference in speech-in-noise intelligibility benefit between the self-fit and the professional-fit groups, as assessed by the QuickSIN, with subjectively comparable score distributions (**Figure 3a and 3b**).

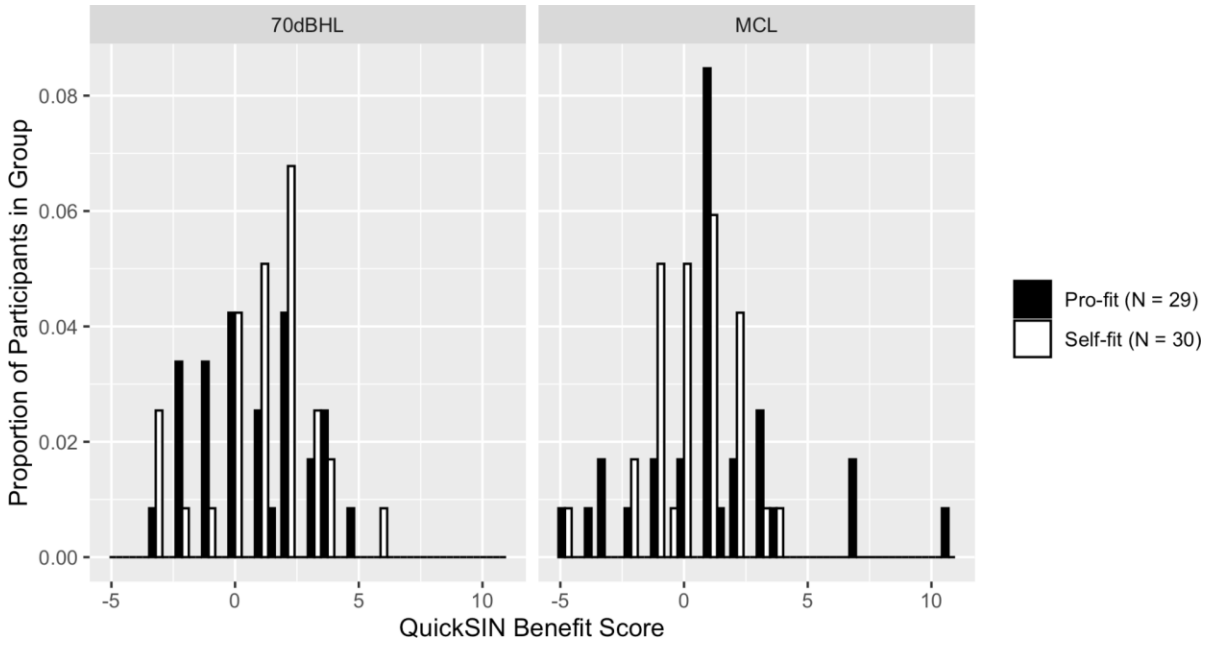


Figure 3a. Distribution of benefit scores (aided score minus unaided baseline score) for the professional (Pro)-fit (red) and self-fit (blue) groups, for the two presentation levels tested (70 dB HL, left panel; MCL, right panel).

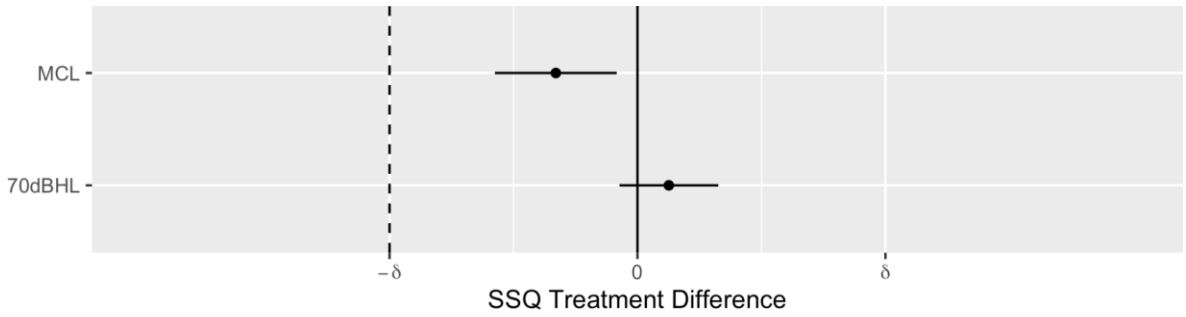


Figure 3b. 95% confidence interval on the difference between self-fit and pro-fit group means for the QuickSIN. The dashed vertical line shows the non-inferiority margin.

Reliability and Validity of the MDHearing Self-Fitting Method:

Real Ear Measures (REMs)

The reliability and validity in-lab (pre- field trial) testing included probe-microphone measures of hearing aid output in the ear canal, expressed either as real ear aided response (REAR) or gain (REAG) depending on the analysis.

Reliability results showed that on successive trials of the self-fitting procedure, the mean absolute difference (MAD) in real-ear measures of average gain was significantly less than 2 dB ($p < 0.001$) for all trial to trial comparisons (Second - First and Third - Second) and at all test frequencies (**Figure 4**).

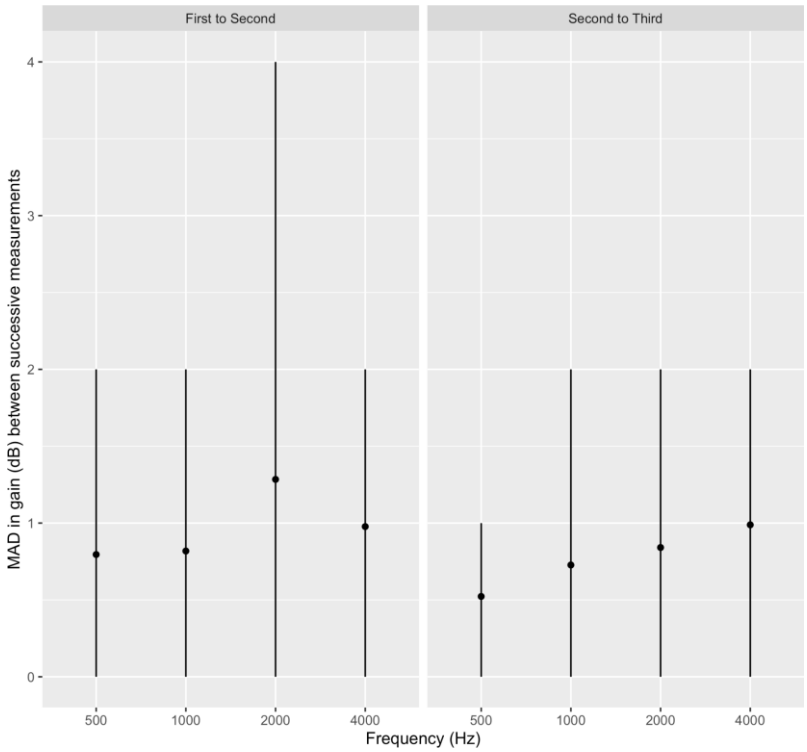


Figure 4. Mean absolute difference (black symbols) in gain as measured from 500-4000 Hz between successive self-fitting measurements. In-lab reliability testing data were obtained on 44 subjects (N = 88 ears). Error bars are 80% intervals (from 10th percentile to 90th percentile).

As a supplementary, qualitative measure of test-retest reliability of the self-fitting method, average in-lab REAG of a subset of participants (those later assigned to the professional-fit group only) was compared to that measured at baseline during their initial hearing aid fittings. The self-selected gain in the reliability test was similar to the user-preferred, fine-tuned gain of the hearing aid fitting as completed by a clinician. (**Figure 5**). This was considered an acceptable estimation of test-retest reliability because, for both measures, the subjective “target” of comfortable loudness and sound quality was the same.

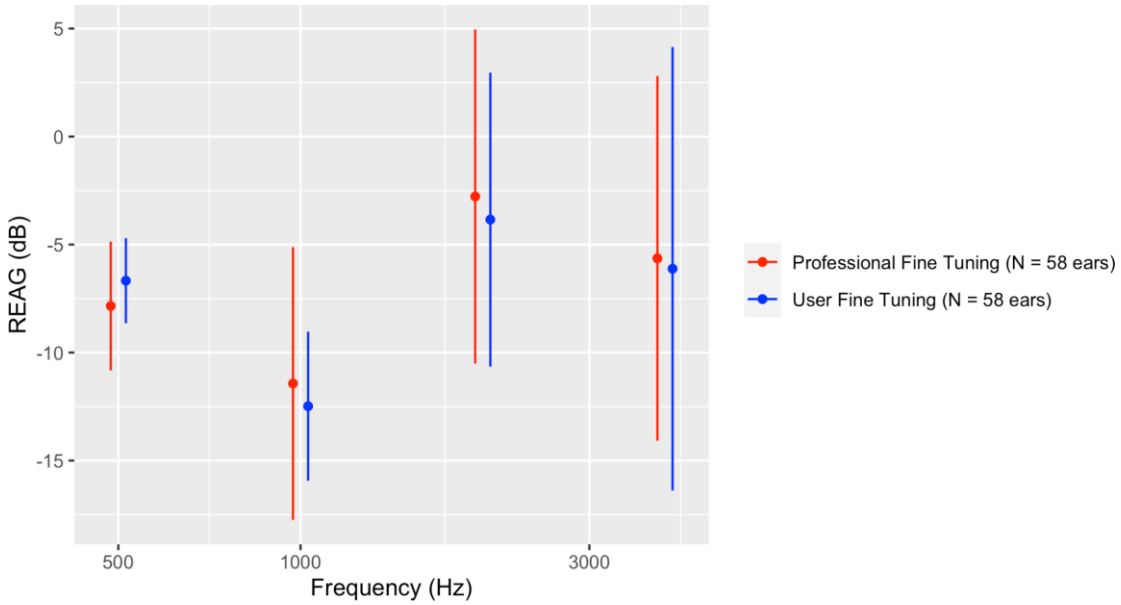


Figure 5. Average REAG from 500-4000 Hz of user-preferred settings as measured during professional-fitting (red) and as self-fit for the in-lab reliability testing procedure (blue). Error bars represent ± 1 standard deviation.

Lastly, analysis of professional-fit participants' real-ear hearing aid output at the time of their initial hearing aid field trial fitting revealed reasonable approximation of REAR to prescribed target levels as measured from 500-4000 Hz, demonstrating that the MDHearing Smart Hearing Aids are capable of delivering adequate amplification to compensate for mild to moderate hearing loss (**Figure 6**).

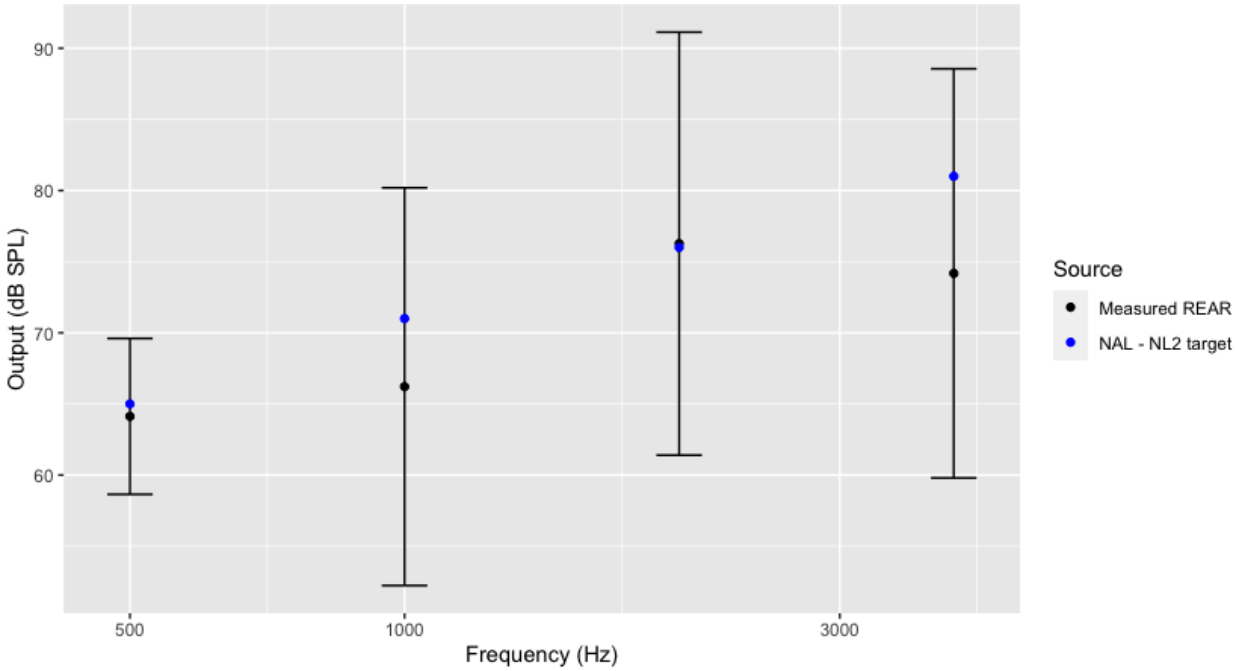


Figure 6. Mean (black symbols) and ± 95% confidence interval (error bars) of the REAR measured when matching to NAL-NL2 prescriptive targets (blue symbols) for average (65 dB SPL) conversational speech input. Targets shown are representative of those based on the average audiometric thresholds at 500, 1000, 2000, and 4000 Hz for the analyzed ears (N=56) of the 28 participants included in this analysis.

Taken together, the baseline REM results of the laboratory reliability testing self-fit procedure and of the professionally derived, target-matched aided response curves (Figures 4-6 above) for a subset of participants fit by a clinician with the MDHearing Smart Hearing Aids demonstrate both reliability and validity of the MDHearing self-fitting method. The final REMs of user-preferred, field-selected hearing aid settings for all participants were analyzed and found to be similar between groups.

Effectiveness

The MDHearing Smart Hearing Aids clinical study focused on determining an equivalence in performance between a fitting by the user of the subject device and a fitting by a hearing care professional. Using methods similar to those used to validate the predicate device, the outcomes compared subjective and objective benefit with the MDHearing Smart Hearing Aids through both quantitative and qualitative measures. The study results demonstrated that the MDHearing Smart Hearing Aid was non-inferior to fitting by a hearing care professional for both subjective and objective measures of hearing aid benefit.. Therefore, the effectiveness of the MDHearing Smart Hearing Aid as a self-fitting, air conduction hearing aid, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment, without the assistance of a hearing care professional, is substantially equivalent to the effectiveness reported for the predicate device, the Bose® Hearing Aid (DEN180026).

Safety

There were no adverse events or serious adverse events reported during the clinical study.

Summary

The MDHearing Smart Hearing Aid was evaluated in a clinical study using both subjective and objective measures commonly used to validate the performance of hearing aid systems and the benefit associated with the hearing aid to the individual user. The results of clinical performance testing provide support for the conclusion that the MDHearing Smart Hearing Aid has a reliable self-fitting method and will provide the intended user population with functional aided performance not inferior to that provided by a professional hearing aid fitting.

X. NON-CLINICAL PERFORMANCE TESTING

Non-clinical performance testing, including human factors testing, was conducted to demonstrate substantial equivalence and to provide reasonable assurance of safety and

effectiveness as compared to the predicate device, the Bose® Hearing Aid, as described in DEN180026. The standards used and results of non-clinical performance testing are summarized in the table below.

Summary of Non-Clinical Performance Testing

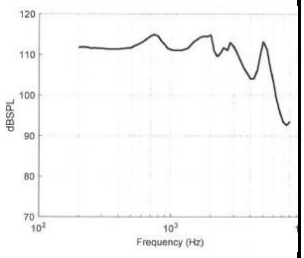
Applicable Standard(s) / FDA Guidance	Test Purpose	Result
IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11:2010 – Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-2-66:2013 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 IEC 60118-13:2019 – Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility	Electromagnetic Compatibility (EMC)	Pass
IEC 62304:2006/AMD 1:2015 00 Medical device software – Software life cycle processes – Amendment 1 ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes FDA-2020-D-0957 (2005)	Software Verification/Validation	Pass
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	Biocompatibility	Pass

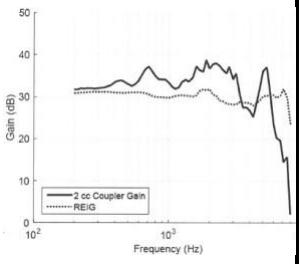
Applicable Standard(s) / FDA Guidance	Test Purpose	Result
ISO 10993-12:2007 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials U.S. Food and Drug Administration Good Laboratory Practice (GLP) 21 CFR Part 58		
IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices 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	Usability	Pass
FDA Guidance FDA-2013-D-0616 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - October 2, 2014	Cybersecurity Compliance	Pass
ISO 14971:2019 – Medical devices – Application of risk management to medical devices FDA 21 CFR 820	Risk Management	Pass
Federal Communications Commission, Part 15 Low Power Communication Device Transmitter IEEE/ANSI C63.27:2017 Evaluation of Wireless Coexistence AAMI TIR 69:2020 Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems	Bluetooth SIG Compliance	Pass
ANSI C63.19:2011 – Methods of Measurement of Compatibility Between Wireless Communication Devices and Hearing Aids	Radio Frequency Immunity	Pass
ANSI ASA S3.22:2014 – Specification of Hearing Aid Characteristics ANSI CTA 2051:2017 – Personal Sound Amplification Performance Criteria IEC 60118-7:2005	Electroacoustic Performance	Pass

NOTE: Full Non-Clinical Performance Testing results, including acceptance criteria and testing performed to internal specifications, are reported in the 510(k) submission.

ANSI ASA S3.22:2014 Measurements:

In order to demonstrate substantial equivalence with the predicate device, the MDHearing Smart Hearing Aid was evaluated per ANSI ASA S3.22 for acoustic performance. The results are summarized below.

Test Specification Applicable Standard (Clause)	**Predicate Device: Bose Hearing Aid (DEN180026)***	**Subject Device: MDHearing Smart Hearing Aid**	**Discussion**
OSPL90 curve ANSI S3.22:2014 (6.2)		See Figure 7	Comparable to predicate and suitable for the intended user. Test method and hearing aid characteristic both in accordance with ANSI S3.22:2014.
MAX OSPL90 ANSI S3.22:2014 (6.2)	115 dB SPL, which is less than or equal to 120 dB SPL	Less than or equal to 120 dB SPL	Comparable to the predicate and suitable for the intended user. Both in conformity to ANSI/CTA-2051.
HFA-OSPL90 ANSI S3.22:2014 (6.3)	112 dB SPL	109 dB SPL	Both adequate for fitting up to moderate hearing loss (55 dB HL) as prescribed by NAL-NL2. Clinical validation study data support substantial equivalence.
HFA FOG ANSI S3.22:2014 (6.5)	43 dB	35 dB SPL	Both adequate for fitting up to moderate hearing loss (55 dB HL) as prescribed by NAL-NL2. Clinical validation study data

Test Specification Applicable Standard (Clause)	**Predicate Device: Bose Hearing Aid (DEN180026)***	**Subject Device: MDHearing Smart Hearing Aid**	**Discussion**
			support substantial equivalence.
RTG ANSI S3.22:2014 (6.7)	36 dB	35 dB	Both adequate for fitting up to moderate hearing loss (55 dB HL) as prescribed by NAL-NL2. Clinical validation study data support substantial equivalence.
Frequency response ANSI S3.22:2014 (6.8)		See Figure 7	Comparable to predicate and suitable for the intended user. Test method and hearing aid characteristic both in accordance with ANSI S3.22.
Frequency response bandwidth ANSI/CTA 2051:2017 (4.1) with underlying test method ANSI S3.22:2014 (6.9)	<200 Hz to >8000 Hz	200 Hz to 7000 Hz	Comparable to the predicate and suitable for the intended user. Both in conformity to ANSI/CTA-2051.
Harmonic Distortion ANSI S3.22:2014 (6.11)	3.6%	500 Hz 3% 800 Hz 1% 1600 Hz 0% THD ≤ 5%	Both in conformity to ANSI/CTA-2051.
EIN ANSI S3.22:2014 (6.12)	26 dB SPL	24 dB SPL	Both in conformity to ANSI/CTA-2051.
Battery Current ANSI S3.22:2014 (6.13)	N/A	1.2 mA	Predicate device was rechargeable.
Estimated Battery	N/A**	Under normal	

Test Specification Applicable Standard (Clause)	**Predicate Device: Bose Hearing Aid (DEN180026)***	**Subject Device: MDHearing Smart Hearing Aid**	**Discussion**
Life ANSI/CTA 2051:2017 (4.7)		operating conditions the size 312 battery lasts around 100 hours prior to replacement.	In conformity to ANSI/CTA-2051.
Latency ANSI/CTA 2051:2017 (4.8)	≤ 15ms**	≤ 15ms	Both in conformity to ANSI/CTA-2051.
Reporting of Hearing Aid Features *ANSI/CTA 2051:2017 (4.10-4.17)*	N/A**	-Fixed or Level Dependent Frequency Equalization -Level Dependent -Gain/Compression -SNR Enhancement -Noise Reduction -Feedback Control/ Cancellation -Personalization -Device Coupling to the Ear -Wireless Connectivity	In conformity to ANSI/CTA-2051.

* The information presented in this table for the predicate Bose Hearing Aid (DEN180026) is as it is reported in K211008 unless otherwise noted.
**Performance of predicate device on this parameter is not publicly available – De Novo Summary for the predicate Bose® Hearing Aid (DEN180026) reports only a test result of “Pass” (per ANSI/CTA-2051) or “Complete” (for parameters with only a reporting requirement and not a performance requirement).

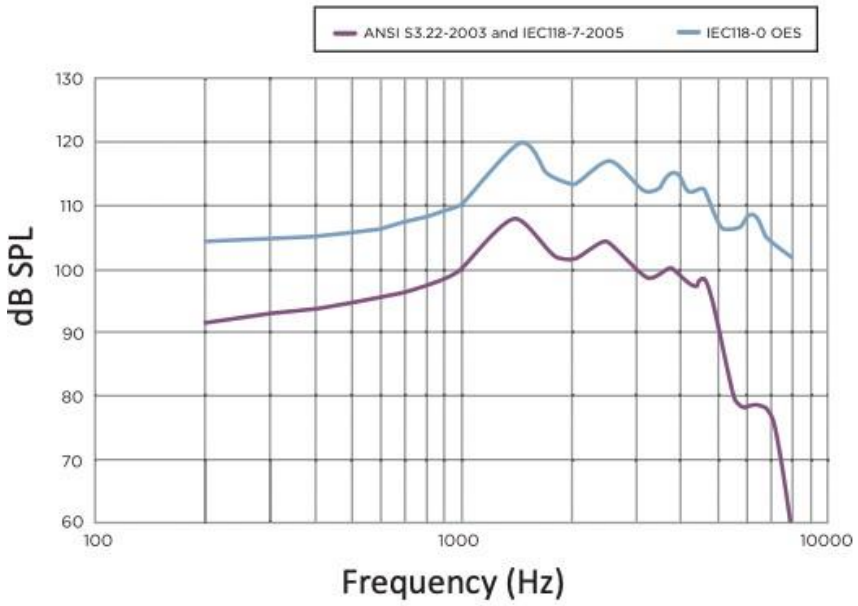


Figure 7. Nominal OSPL90 (blue) and frequency response (purple) curves for MDHearing Smart Hearing Aid as measured in 2cc coupler. Note: ANSI S3.22 and IEC 60118-7 standard specifications are technically equivalent for the electroacoustic parameters required as special controls.

The results of all performance testing required as special controls demonstrated substantial equivalence of the MDHearing Smart Hearing Aid to the predicate Bose Hearing Aid. The MDHearing Smart Hearing Aid has the same intended use and fundamental technology as the predicate. The differences in technological characteristics do not raise different questions of safety or effectiveness.

Usability Testing:

In order to evaluate the usability and safety of the MDHearing Smart Hearing Aid, a human factors study was conducted with 20 untrained participants representing the intended user population of the devices (individuals 18 years of age or older with perceived mild to moderate hearing impairment). This study was conducted in accordance with FDA's guidance, Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff (2016). The overall aim of the human factors study was to qualitatively assess a population of representative users' ability to safely operate the MDHearing Smart Hearing Aids and app without any assistance from a hearing care professional.

Each participant was provided a pair of MDHearing Smart Hearing Aids, new in the box, with all standard accessories and user manuals for the devices included, and experimenters observed and assessed participants' completion of the following hands-on use tasks:

- Unbox the MDHearing Smart Hearing Aids
- Download the MDHearing app to personal smartphone.
- Register for the app.
- Place batteries in the hearing aids.

- Use the app to pair the hearing aids to the smartphone via Bluetooth.
- Use the app to take the personalization profile.
- Use the app to adjust the volume, program, noise reduction, microphone direction, bass, treble, and mid pitched settings.
- Turn off the hearing aids.

A self-identification questionnaire, designed to evaluate participants' general knowledge regarding hearing health issues and the circumstances under which it may be appropriate to seek help from a professional, was completed as part of the study procedure. Participants' ability to self-fit the hearing aids using the app and to achieve a proper physical fit of the devices with included ear tips was also observed as part of the above hands-on use scenarios.

The results of the human factors validation testing showed that the MDHearing Smart Hearing Aids are safe and operable for intended users, uses, and use environments.

XI. CYBERSECURITY

The MDHearing Smart Hearing Aids and the Intricon-provided cloud based fitting solution was determined to have appropriate safety tools and controls such that the risk of a security breach is negligible. The risks are acceptable and reduced as far as possible.

The MDHearing app and cloud-based application was determined to have appropriate safety tools and controls such that the risk of a cybersecurity breach is negligible. The risks are acceptable and reduced as far as possible.

Due to the negligible risk, no special labeling is deemed necessary regarding cybersecurity controls in the instructions for use. The labeling in the instructions for use is appropriate for the intended use environment, which is an at-home environment.

Due to negligible risk, no special product specifications related to cybersecurity controls are needed.

XII. CONCLUSION

The MDHearing Smart Hearing Aid is substantially equivalent in intended use to the Bose® Hearing Aid (DEN180026). The non-clinical testing and performance data verify the safety and effectiveness of the subject device, and the hardware and software verification and validation demonstrate that the MDHearing Smart Hearing Aid should perform as intended in the specified use conditions. The human factors study demonstrated that the usability of the MDHearing Smart Hearing Aid was analyzed, verified, and validated for its intended use, and the implemented mitigations for user training and device labeling are adequate. The clinical data showed similar results in subjective and objective measures between subjects who self-fit and were professionally fit with the MDHearing Smart Hearing Aid. The clinical data validates that the MDHearing Smart Hearing Aid performs comparably to the predicate device, the Bose®

Hearing Aid as outlined in DEN180026. Together, these performance data support that the MDHearing Smart Hearing Aid is substantially equivalent in intended use to the predicate device, the Bose® Hearing Aid (DEN180026), and is as safe and as effective for its intended use when used in accordance with its Instructions for Use.