June 16, 2023

Sonova AG
% Philip Won
Associate
Hymann, Phelps, & McNamara, P.C.
700 13th Street N.W
Suite 1200
Washington DC, District of Columbia 20005

Re: K230538
Trade/Device Name: All-Day Clear Slim ADCS1 Hearing Aid. All-Day Clear ADC1 Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QUH
Dated: May 19, 2023
Received: May 19, 2023

Dear Philip Won:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shuchen Peng -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K230538

Device Name
All-Day Clear ADC1 hearing aid

Indications for Use *(Describe)*
The All-Day Clear hearing aids are intended for individuals 18 years or older with perceived mild to moderate hearing loss. The intended use of the All-Day Clear hearing aids is to amplify and transmit sound to the ears and hereby compensate for hearing loss. The hearing aids must only be used by the intended person. They should not be used by any other person as they could damage hearing. The charging case is intended to charge the battery of the rechargeable hearing aids. The All-Day Clear App is intended for individuals 18 years or older, to set-up and/or adjust All-Day Clear hearing aids through Android and Apple iOS smartphones.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K230538

Device Name
All-Day Clear Slim ADCS1 hearing aid

Indications for Use *(Describe)*
The All-Day Clear Slim hearing aids are intended for individuals 18 years or older with perceived mild to moderate hearing loss. The intended use of the All-Day Clear Slim hearing aids is to amplify and transmit sound to the ears and hereby compensate for hearing loss. The hearing aids must only be used by the intended person. They should not be used by any other person as they could damage hearing. The charging case is intended to charge the battery of the rechargeable hearing aids. The All-Day Clear App is intended for individuals 18 years or older, to set-up and/or adjust All-Day Clear Slim hearing aids through Android and Apple iOS smartphones.

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)

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: JUNE 16, 2023

SUBMITTER:

Sonova AG
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Staefa, Zurich 8712
Switzerland

PRIMARY CONTACT PERSON:

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DEVICE NAME AND CLASSIFICATION:

TRADE NAME:	All-Day Clear Slim ADCS1 hearing aid All-Day Clear ADC1 hearing aid
COMMON/USUAL NAME:	OTC Self-fitting Hearing Aid
CLASSIFICATION NAMES:	Self-fitting Air-Conduction Hearing Aid
REGULATION NUMBER:	21 C.F.R. § 874.3325
PRODUCT CODE:	QUH
CLASSIFICATION:	Class II
REVIEW PANEL:	Ear, Nose, and Throat

PREDICATE DEVICE:

Bose SoundControl Hearing Aid (K211008)

DEVICE DESCRIPTION:

The All-Day Clear Slim ADCS1 hearing aid and All-Day Clear ADC1 hearing aid are self-fitting air-conduction hearing aids. The ADCS1 and ADC1 hearing aids are nearly identical except for minor design differences. The hearing aid system consists of hearing aids for left and right ears, charging case, charging cable with USB-A and USB-C connector, wall plug, a set of eartips (small, medium, and large sizes), cleaning brush, carrying case (for ADCS1 hearing aids alone), and wax guards. The ADCS1 and ADC1 hearing aids are indicated for over-the-counter use.

The end user can self-fit the hearing aid by downloading the All-Day Clear App to their Android or Apple iOS device, pairing the hearing aids to the App, and following a series of guided onboarding steps:

- Instructions on how to wear the hearing aids
- Creation of a sound profile by listening to sample audio in which the user selects parameters for volume and sound clarity
- Selection of sound balance

Once the hearing aids have been set up with a sound profile, the App can continue to be used as a remote control of the hearing aids. For example, the end users can use the App to change the volume or mute the hearing aid microphones (together or independently), switch between different hearing aid sound modes, adjust the volume of a streamed signal, adjust equalizer and wind noise control, and read out the status of the hearing aid charge level.

The ADCS1 and ADC1 hearing aid system provides an alternative optional method of fitting the device by letting the end users purchase “In-Clinic Care Package”, where they can have a licensed hearing care professional fit their hearing aids using professional fitting software called “All-Day Clear Fitting Software.” All-Day Clear Fitting Software is a component of Sonova’s TrueFit 5.3 or higher fitting software which can only be used by a licensed hearing care professional. In both scenarios, the end users can use the App as a remote control of the hearing aid.

INTENDED USE:

All-Day Clear Slim ADCS1 hearing aid: All-Day Clear Slim hearing aids are intended for individuals 18 years and older with perceived mild to moderate hearing loss.

All-Day Clear ADC1 hearing aid: All-Day Clear hearing aids are intended for individuals 18 years and older with perceived mild to moderate hearing loss.

INDICATIONS FOR USE:

All-Day Clear Slim ADCS1 hearing aid: The All-Day Clear Slim hearing aids are intended for individuals 18 years or older with perceived mild to moderate hearing loss. The intended use of the All-Day Clear Slim hearing aids is to amplify and transmit sound to the ears and hereby compensate for hearing loss. The hearing aids must only be used by the intended person. They should not be used by any other person as they could damage hearing. The charging case is intended to charge the battery of the rechargeable hearing aids. The All-Day Clear App is intended for individuals 18 years or older, to set-up and/or adjust All-Day Clear Slim hearing aids through Android and Apple iOS smartphones.

All-Day Clear ADC1 hearing aid: The All-Day Clear hearing aids are intended for individuals 18 years or older with perceived mild to moderate hearing loss. The intended use of the All-Day Clear hearing aids is to amplify and transmit sound to the ears and hereby compensate for hearing loss. The hearing aids must only be used by the intended person. They should not be used by any other person as they could damage hearing. The charging case is intended to charge the battery of the rechargeable hearing aids. The All-Day Clear App is intended for individuals 18 years or older, to set-up and/or adjust All-Day Clear hearing aids through Android and Apple iOS smartphones.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the subject device (ADCS1 and ADC1 hearing aids) and the predicate device (Bose SoundControl Hearing Aids) are self-fitting hearing aids indicated for individuals 18 and older with perceived mild to moderate hearing impairment. The same fundamental technology is present in both hearing aids to allow the user to control and customize the device to the user's hearing needs.

Both devices are receiver-in-canal (RIC) hearing aids designed for all-day wear. While there are some technical differences between the Sonova and Bose devices they do not introduce different questions of safety or effectiveness. The key similarities and differences between the Sonova ADCS1/ADC1 hearing aids and the Bose SoundControl hearing aids are summarized in Table 1.

Table 1. Comparison of technical characteristics of Sonova ADCS1/ADC1 hearing aids and Bose SoundControl hearing aids.

	Sonova ADCS1 Hearing Aids (Subject Device)	**Sonova ADC1 Hearing Aids (Subject Device)**	**Bose SoundControl Hearing Aids (K211008, Predicate Device)**	**Discussion**
Product Code	QUH	QUH	QDD	**Different.** The product code QUH reflects the OTC status of the device, and the product code QDD reflects a restricted direct-to-consumer device was in use prior to the passage of the OTC hearing aid rule.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Intended Use	All-Day Clear Slim hearing aids are intended for individuals 18 years and older with perceived mild to moderate hearing loss.	All-Day Clear hearing aids are intended for individuals 18 years and older with perceived mild to moderate hearing loss.	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.	**Identical.**

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Indications For Use	The All-Day Clear Slim hearing aids are intended for individuals 18 years or older with perceived mild to moderate hearing loss. The intended use of the All-Day Clear Slim hearing aids is to amplify and transmit sound to the ears and hereby compensate for hearing loss. The hearing aids must only be used by the intended person. They should not be used by any other person as they could damage hearing. The charging case is intended to charge the battery of the rechargeable hearing aids. The All-Day Clear App is intended for individuals 18 years or older, to set-up and/or adjust All-Day Clear Slim hearing aids through Android and Apple iOS smartphones.	The All-Day Clear hearing aids are intended for individuals 18 years or older with perceived mild to moderate hearing loss. The intended use of the All-Day Clear hearing aids is to amplify and transmit sound to the ears and hereby compensate for hearing loss. The hearing aids must only be used by the intended person. They should not be used by any other person as they could damage hearing. The charging case is intended to charge the battery of the rechargeable hearing aids. The All-Day Clear App is intended for individuals 18 years or older, to set-up and/or adjust All-Day Clear hearing aids through Android and Apple iOS smartphones.	The Bose SoundControl™ Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.	**Comparable to predicate.** Both devices are indicated for individuals 18 years and older with perceived mild to moderate hearing loss. The ADCS1/ADC1 hearing aids are intended for the over-the-counter use.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Device description	Sonova ADCS1 hearing aids amplify and transmit sound to the ears and thereby compensate for perceived mild to moderate hearing loss. The users can self-fit the ADCS1 hearing aids using the All-Day Clear App by selecting a Sound Profile in the App.	Sonova ADC1 hearing aids amplify and transmit sound to the ears and thereby compensate for perceived mild to moderate hearing loss. The users can self-fit the ADC1 hearing aids using the All-Day Clear App by selecting a Sound Profile in the App.	Bose SoundControl hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings. The device consists of the hardware, software, the Bose Hear app, and accessories.	**Comparable to predicate.** Both the subject and predicate devices include hearing aid hardware, software, and accessories.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Battery	Rechargeable battery	Rechargeable battery	Disposable size 312 zinc-air battery	**Different.** A different type of battery does not raise different questions of safety and effectiveness. The battery safety tests demonstrated that the subject device is as safe and effective as the predicate devices with respect to the battery.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Max OSPL90	109 dB SPL	110 dB SPL	113 dB SPL	**Comparable to predicate**. The subject device has a lower Max OSPL90 than the predicate device, indicating that it is as safe as the predicate device. A one or four dB SPL difference of the Max OSPL90 compared to the predicate device does not raise different questions of effectiveness as demonstrated by the clinical study.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
High-frequency average (HFA) OSPL90	103 dB SPL	106 dB SPL	106 dB SPL	**Comparable to predicate**. Devices are equivalent in safety by having an equal or lower value. A one or three dB SPL difference compared to the predicate device does not raise different questions of effectiveness as demonstrated by the clinical study.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
HFA full on gain (FOG)	29 dB	29 dB	30 dB	**Comparable to predicate**. Devices are equivalent in safety by having an equal or lower value. A one dB SPL difference compared to the predicate device does not raise different questions of effectiveness as demonstrated by the clinical study.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Reference test gain (RTG)	26 dB	29 dB	29 dB	**Comparable to predicate**. Devices are equivalent in safety by having an equal or lower value. A one or three dB SPL difference compared to the predicate device does not raise different questions of effectiveness as demonstrated by the clinical study.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Frequency range	100 – 8,000 Hz	100 – 5,000 Hz * *This is the bandwidth measured with the method as specified in ANSI/CTA-2051:2017. When measured with the method as specified in ANSI/ASA S3.22-2014, the bandwidth for ADC1 hearing aids is 100 – 10,000 Hz.	200 – 8,000 Hz	**Comparable to predicate**. Values meet the same ANSI/CTA-2051:2017 standard for "Standard Band" device.

	Sonova ADCS1 Hearing Aids (Subject Device)	Sonova ADC1 Hearing Aids (Subject Device)	Bose SoundControl Hearing Aids (K211008, Predicate Device)	Discussion
Harmonic Distortion	THD @ 500 Hz: 0.5% THD @ 800 Hz: 0.5% THD @ 1,600 Hz: 1.0% THD @ 3,200 Hz: 1.0%	THD @ 500 Hz: 1.0% THD @ 800 Hz: 1.0% THD @ 1,600 Hz: 1.0% THD @ 3,200 Hz: 0.5%	< 1%	**Comparable to predicate.** Values are either equal or do not exceed 1%. The ANSI/ASA S3.22-2014 specification for Harmonic Distortion allows the manufacturer a tolerance of 3% for this measurement. Thus, our values are comparable.
Equivalent input noise (EIN)	19 dB SPL	19 dB SPL	< 27 dB SPL	**Comparable to predicate.** Values do not exceed 27 dB SPL.

PERFORMANCE DATA:

Summary of Non-Clinical Tests

Sonova AG conducted a series of non-clinical performance testing to demonstrate that the Sonova ADCS1/ADC1 Hearing Aids are as safe and effective as the Bose SoundControl Hearing Aid. The results are summarized in Table 2 below. Note that the same set of non-clinical performance testing was reported for the predicate Bose SoundControl hearing aid (K211008).

Table 2. Non-Clinical performance tests for the ADCS1/ADC1 Hearing Aids.

Test	Test Standard / Method	Result
Electrical Safety	• IEC-60601-1: 2005 + Corr.1: 2006 + Corr.2.:2008 + A1:2012 • ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 • IEC 60601-2-66:2019	Pass
Electromagnetic Compatibility (EMC)	• IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION •	Fail (*see the note below)
	• ANSI C63.19-2019	Pass
	• IEC 60118-13:2020	Pass
	• FCC: CFR 47, Part 15, Subpart B, (10-1-19) & ICES-003 Issue 6 (Updated 2019-04)	Pass
RF Testing	• FCC 1093 47 CFR Part 2 • FCC 47 CFR Part 15.249, RSS-210 Issue 9	Pass
Biocompatibility	• ISO 10993-1:2018	Pass
Human Factors and Usability Engineering	• The summative human factors study was performed following the FDA guidance document entitled "Applying Human Factors and Usability Engineering to Medical Devices."	Pass

Test	Test Standard / Method	Result
Software	• ISO 14971:2019 Medical Devices– Application of Risk Management	Pass
Electroacoustic Performance	• ANSI/CTA-2051:2017	Pass

* The ADCS1 hearing aid samples for electrostatic discharge (ESD) immunity failed for the direct contact discharge at ±8kV. The ADC1 hearing aid samples for ESD immunity failed for the air discharge at ±15kV and for the direct contact discharge at ±8kV. The sample devices became inoperable after these ESD exposures. Per the EMC/ESD testing, the ADCS1 and ADC1 hearing aids do not pose a safety risk and they are as safe and effective as the predicate devices because (1) except for these testing conditions, the ADCS1 and ADC1 hearing aids passed the rest of the tests per IEC 60601-1-2, (2) none of the failed sample devices showed signs of visible damage, melting, fire, or explosion, (3) a type of ESD protection circuitry is implemented in the ADCS1/ADC1 hearing aids and (4) the supplied LiION batteries for the ADCS1 and ADC1 hearing aids meet the battery standards UN38.3 and UL1642. Finally, the labeling instructs users to return any non-functional or damaged devices for service.

Summary of Human Factors / Usability Tests

The primary objective of the human factors usability validation study was to investigate whether the ADCS1/ADC1 hearing aids and the companion mobile App could be used as intended by adult patients and caregivers in a simulated use environment. This study determined if first-time end users could appropriately use the ADCS1/ADC1 device design, labeling, instructional materials, mobile phone application, and packaging such that use errors or difficulties that could result in harm were avoided. This study investigated the respective root causes and potential outcomes for use errors that occurred or almost occurred (i.e., close call).

The intended demographic for this study was adult patients with perceived mild to moderate hearing loss and caregivers of patients with perceived mild to moderate hearing loss. Thirty participants were enrolled in the study−fifteen patients and fifteen caregivers. Participants were asked to complete tasks in a simulated use environment associated with self-selecting, setting up, and using the ADCS1/ADC1 hearing aids. During the study session, study staff systematically assessed device usage to identify problems that were encountered by participants, including use errors and close calls during participant performance. Use-error evaluations of the device included both

objective (performance-based) and subjective (user-feedback) evaluations of success for completing the tasks identified as critical for appropriate and safe use.

The results of this human factors usability validation study indicate effective self-selection of the ADCS1/ADC1 hearing aids by inexperienced adults with perceived mild to moderate hearing loss and inexperienced caregivers of adults with perceived mild to moderate hearing loss. All 30 participants were able to use the package information to decide if the device was appropriate or not appropriate for them or the person they care for to use. This study also demonstrated the safe use of the ADCS1/ADC1 hearing aids for inexperienced adults with perceived mild to moderate hearing loss and inexperienced caregivers of adults with perceived mild to moderate hearing loss.

Summary of Clinical Tests

Background: Sonova AG performed the clinical study to demonstrate the effectiveness of the self-fitting strategy for adults with mild to moderate hearing impairment compared to a professionally derived fitting. Sonova AG used the device "HelloGO" hearing aid for this clinical study. All Day Clear Slim is a re-branded HelloGo device with identical hardware and almost identical firmware. Based on the comparison and evaluation of the devices with respect to the technical, material, labeling, and clinical characteristics, it is reasonable to conclude that the three devices (ADCS1, ADC1, and HelloGO) are equivalent and there are no significant differences regarding safety and effectiveness of the devices.

Study Endpoints:

- The primary effectiveness endpoint: Non-inferiority of the Abbreviated Profile of Hearing Aid Benefit (APHAB) global benefit score for self-fit the devices versus professionally fit devices.
- The secondary effectiveness endpoint: Non-inferiority of the Quick Speech-in-Noise (QuickSiN) test benefit score for self-fit devices versus professionally fit devices.
- The safety endpoint: A tabulation of all adverse events (AEs) and serious adverse events (SAEs) during the study.
- Exploratory endpoints:
    - Wearing comfort questionnaire
    - Net promoter score
    - Real ear aided response (REAR)

Participants: A total of 44 participants were enrolled. There were 19 females enrolled in the study and 25 males, and the average age was 68 years with a range between 22 and 80 years. Thirty-four participants (77.27%) were new users of hearing devices, and 10

participants (22.7%) were current owners of hearing aids. **Figure 1** shows average pure tone air conduction thresholds for the study participants.

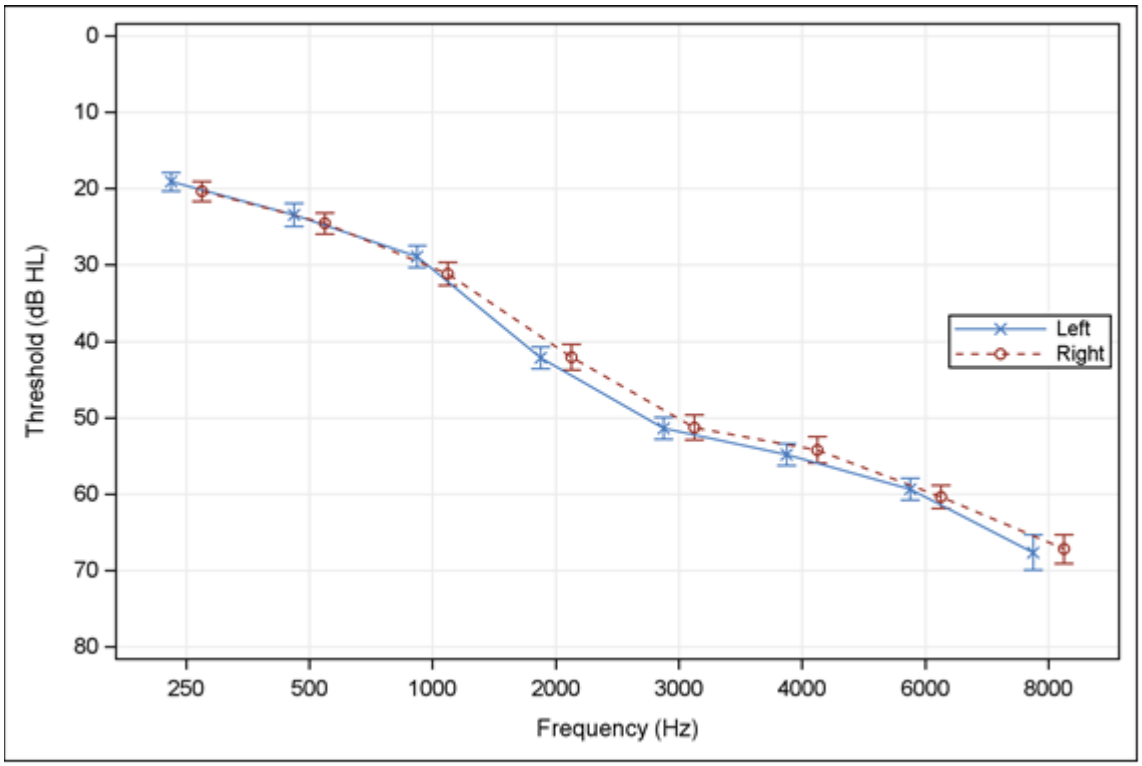

FIGURE 1. AVERAGE PURE TONE AIR CONDUCTION THRESHOLDS FOR THE STUDY PARTICIPANTS

<u>Study Design</u>: A double-blind, cross-over study as shown in **Figure 2**.

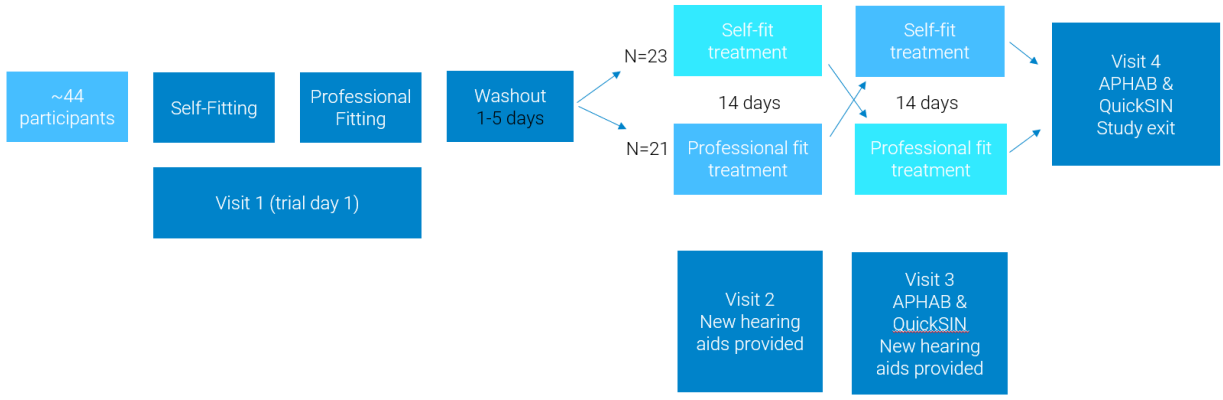

FIGURE 2. STUDY FLOW DIAGRAM SUMMARIZING THE SEQUENCE OF EVENTS FOR EACH PARTICIPANT.

The 44 participants were randomized into one of the following two treatment sequence groups for the cross-over study.

- 23 participants for Professional Fit / Self-Fit (A/B)
- 21 participants for Self-Fit / Professional Fit (B/A)

Four participants were early discontinued (two in each group). These participants did not introduce bias that would affect the validity of the results for the following reasons:

1) Two of the four early-discontinued participants never began a home trial, therefore no aided data was collected for either fitting method.

2) Participant #21 completed period 1 using the professionally fit method, while participant #22 completed period 1 using the self-fitting method. Neither participant continued with the second fitting, therefore only period 1 aided data was collected. The aided APHAB and QuickSiN scores for period 1 for each participant were similar, and because there was one representative from each group, the scores offset each other and did not affect the validity of the results.

At visit 1, all participants were fit with two sets of devices: one set was professionally fit and one set was self-fit. Participants downloaded the App at this visit and were given the opportunity to self-adjust the devices according to their preferences. Participants were not given any devices at this time. Rather, a wash-out period of 1-5 days occurred and as participants returned for visit 2. Participants were blinded as to which device they were given for the first home trial.

Participants returned for visit 3 after a 2-week home trial period and completed the APHAB, QuickSiN and a blinding assessment. Upon completion of these assessments, the first set of devices was collected, and the second set of devices was dispensed as per the treatment schedule. Following another two-week home trial, participants returned for visit 4 to complete the assessments.

Results:

Primary Effectiveness Endpoint: APHAB Global Benefit Score

The APHAB global benefit score is defined as the aided APHAB global scores (one each for self-fit versus professional fit) subtracted from the unaided/baseline APHAB global scores. A higher score indicates greater improvement with the devices. It was hypothesized that the benefit of the self-fitting method would be non-inferior to the benefit of the professional fitting method if the mean APHAB global benefit score for the self-fitting method was no more than 12.5% below the mean APHAB global benefit score

for the professional fit method. This hypothesis was tested using a mixed model with the following variables.

- The dependent variable: APHAB global benefit score
- Fixed effects: Treatment sequence, period, and treatment
- Random effect: participants
- Covariate: First-period baseline performance

The adjusted mean treatment difference from the mixed model was 0.5%, with a 95% confidence interval ranging from -3.4% to 4.4%. While this finding supports the claim of non-inferior APHAB outcomes with the self-fitting relative to the professional-fitting, the model also found a significant effect of treatment sequence. To further explore this potential effect, an additional analysis of Period 1 data only was conducted, in accordance with the Statistical Analysis plan. The Period 1 analysis was initially inconclusive, as the adjusted mean treatment difference from the mixed model was 0.024 with a 95% confidence interval ranging from -17.937 to -1.252. Non-inferiority could not be concluded because the lower bound of the confidence interval (CI) was less than the non-inferiority margin of -12.5%. Upon further inspection of the APHAB data, however, two outliers were identified. Both were in the Professionally Fit group in Period 1, and were identified as outliers for their unusually high unaided scores for the subscale "Background Noise" (scores of 87 and 91). Given that the mean score for this sub-scale was 44.09302 and SD was 18.1368, these two participants were excluded because their score was greater than 2 SDs above the mean. This indicates that these two subjects experienced unusually high degrees of perceived difficulty understanding speech in background noise in the baseline condition. These high unaided scores impacted their resulting aided benefit, which we believe led to the inconclusive result for non-inferiority when analyzing Period 1 data for the APHAB.

Upon reanalysis excluding these two outliers, the adjusted mean treatment difference for the APHAB Global Benefit score was 0.6%, with a 95% confidence interval ranging from -2.919 to 4.742, and the treatment sequence term is no longer significant. Therefore, non-inferiority can be concluded because the lower bound of this confidence interval is greater than the non-inferiority margin.

Figure 3 shows the scatter plot of the APHAB Global Benefit scores for 40 participants. The dotted line shows one-to-one correspondence.

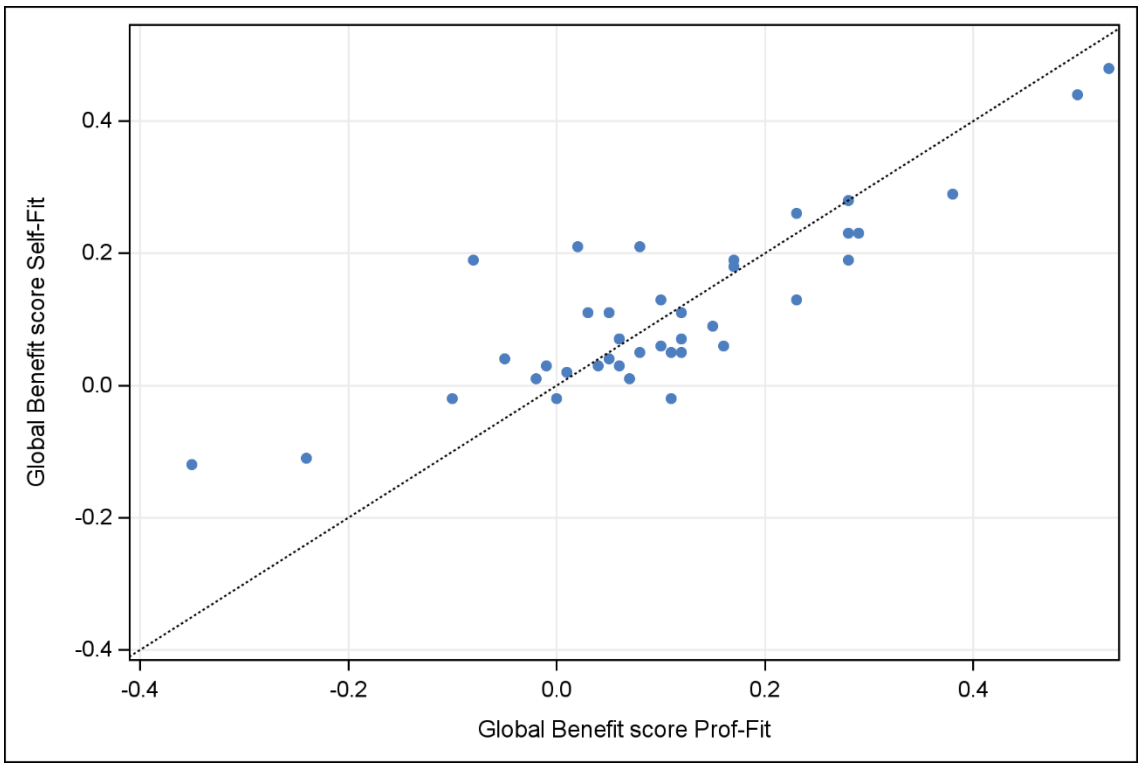

FIGURE 3. SCATTER PLOT OF APHAB GLOBAL BENEFIT SCORES FOR 40 PARTICIPANTS.

Secondary Effectiveness Endpoint: QuickSiN Benefit Score

The QuickSiN test is an objective measure of speech intelligibility in a noisy environment. The QuickSiN is performed in both unaided and aided conditions. The dB SNR (Signal to Noise Ratio) loss is expressed by the SNR at which the participant correctly repeats 50% of the words presented. A lower dB SNR score indicates better speech perception in noise. The QuickSiN benefit score is defined as the aided QuickSiN scores (one each for self-fit versus professional fit) subtracted from the unaided/baseline QuickSiN scores. It was hypothesized that the benefit of the self-fitting method would be non-inferior to the benefit of the professional fitting method if the difference was -1.8 dB or higher. This hypothesis was tested using a mixed model.

The adjusted mean treatment difference from the mixed model was 0.046 dB SNR, with a 95% confidence interval ranging from -0.597 to 0.688 dB SNR. Although the treatment sequence term in this model was *not* significant, an analysis of Period 1 data only was conducted to remain consistent with the approach applied to the APHAB data. Re-analysis using Period 1 data only resulted in an adjusted mean treatment difference of 0.103 dB SNR, with a 95% confidence interval ranging from -0.867 to 1.074. **Non-inferiority was concluded by observing that the lower bound of this confidence**

interval was greater than the non-inferiority margin of -1.8 dB SNR. Figure 4 shows the scatter plot of the QuickSiN benefit scores for 40 participants.

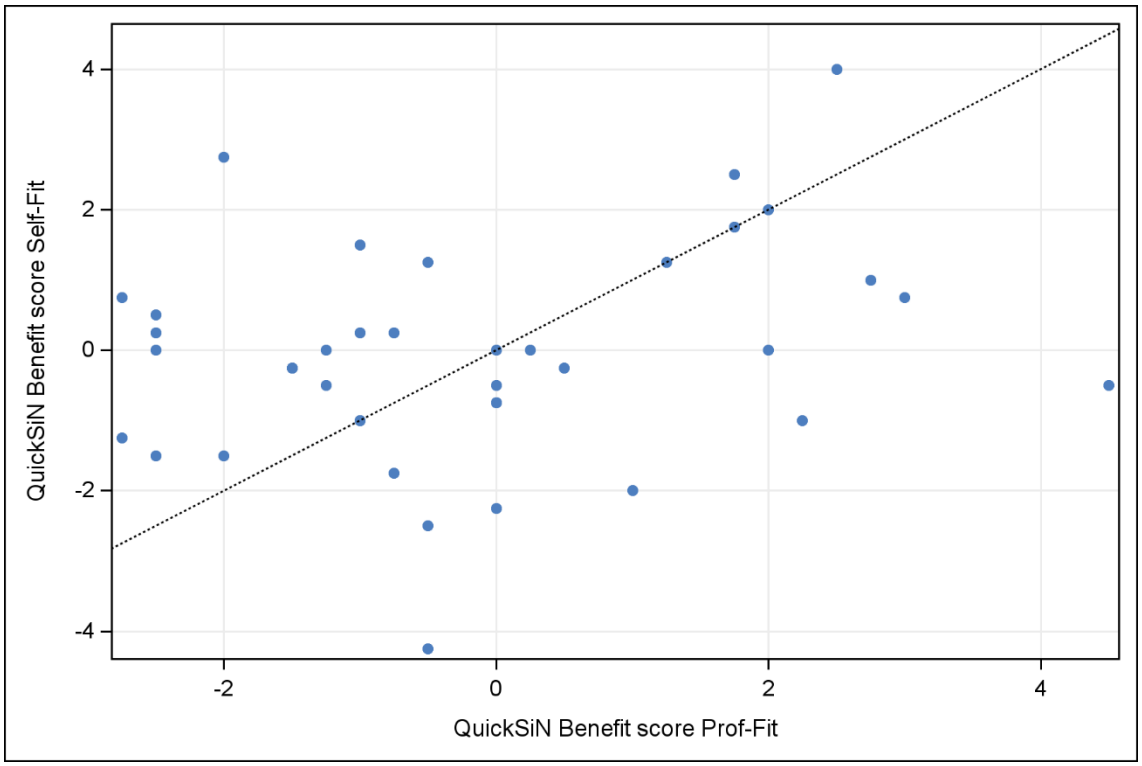

FIGURE 4. SCATTER PLOT OF QUICKSIN BENEFIT SCORES FOR 40 PARTICIPANTS.

The safety endpoint: A tabulation of all adverse events and serious adverse events during the clinical study.

Finally, it is important to note that the design of the study allowed each subject to serve as his or her own control. The full analysis of APHAB data from both periods relied on within-subjects comparisons to draw the conclusion that the self-fitting approach was non-inferior relative to the professional-fitting approach. When examining Period 1 data alone, the analysis is, by definition, a between-subjects analysis. In this analysis, a difference between the group beginning one fitting method relative to the other may suggest inferior performance, irrespective of whether the self-fitting method was truly inferior for the sample in the population on a within-subjects level. Outcomes with hearing aids can vary widely (evident in the standard deviation of the primary endpoint for both treatments). That the group beginning with one treatment had a significantly higher mean benefit than the group beginning with the other treatment is not necessarily a reflection of a treatment difference. It is, instead, likely a manifestation of

the variability in hearing aid outcomes. Further evidence of this may be seen in the Period 2 data. Period 2 results are almost a perfect mirror of the Period 1 outcomes, demonstrating that subjects did not experience a treatment difference during the course of the study. Had a true carryover effect been present, a more likely pattern would be to see a different level of benefit in the Period 2 data for one group than the other; this pattern was not seen in our data.

There was one treatment-emergent adverse event reported in the self-fit group. Subject 01 reported an ear canal occlusion in between Visit 2 and Visit 3. During the first home trial, while fitted with the self-fit hearing aid, the participant used over-the-counter ear drops. The ear drops were reportedly for cerumen removal, but the participant appeared to use the drops incorrectly, which resulted in an inflamed tympanic membrane. This event was not serious and required no action to be taken. The participant was able to complete the study. There were no serious adverse events. The clinical study demonstrated that the ADCS1/ADC1 hearing aids are as safe as the predicate Bose SoundControl hearing aids.

Exploratory Endpoints

- Wearing comfort questionnaire: Of 44 enrolled participants, 93.2% (N = 41) completed a questionnaire regarding the physical comfort of the device. Overall, the majority of participants rated all questions with a response of "Comfortable" or "Very Comfortable." Sixty-four percent of the Professional Fit participants in Period 1 rated the wearing comfort of the BTE piece as either comfortable or very comfortable, and 58% of the Self-Fit participants in Period 1 rated it as comfortable or very comfortable. This is similar to both Period 2 and overall data.

- Net promoter score: Of 44 enrolled participants, 93.2% (N = 41) completed a Net Promotor Score questionnaire. This questionnaire asked participants to rate, on a scale of 0 to 10 (10 is best), how likely they would be to recommend the devices to a friend or family member. A rating of 9 or 10 constitutes a "promotor." In summary, 26.1% of participants were categorized as "promotors." Period 1 data shows that 32% of the Professional Fit participants and 21% of the Self Fit participants were considered "promotors". These percentages were reversed for the overall NPS data which indicates that those who started as promotors remained promotors throughout the study.

- Real Ear Aided Response (REAR): Of 44 enrolled participants, 97.7% (N = 43) completed REAR measurements. In summary, the average response at 1000, 1600, and 2500 Hz was approximately 3 dB lower for the self-fit frequency response compared to the professionally fit response as shown in **Figure 5** below.

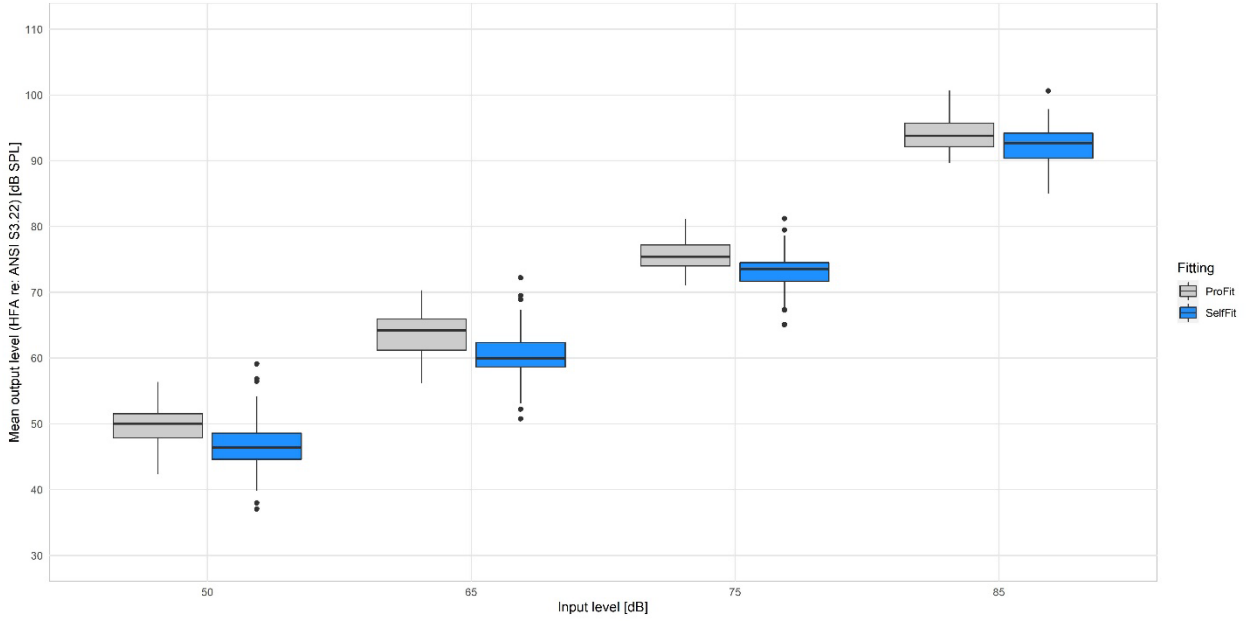

FIGURE 5 REAL EAR-AIDED RESPONSE FOR PROFESSIONAL FIT VS SELF-FIT

In summary, an analysis of Period 1 data shows non-inferior results for self-fitting on the QuickSiN, as well as consistent results between self-fitting and professional fitting on two exploratory endpoints (physical comfort and Net Promotor Score). While the Period 1 analysis of APHAB did not support non-inferiority, it was observed that two study participants with extreme baseline scores for the "Background Noise" subscale of the APHAB were both assigned to begin the study with the professional fitting. A reanalysis of the APHAB results from both Period 1 and 2 that excluded these participants supported non-inferiority of the self-fitting relative to professional fitting while removing the previously significant term for treatment sequence, confirming that the significant treatment sequence finding in the original analysis was highly sensitive to the presence of the two outliers. Taken together, these findings support the non-inferiority of the self-fitting relative to the professional fitting.

CONCLUSION:

Sonova AG demonstrates that the All-Day Clear Slim hearing aids and the All-Day Clear hearing aids are as safe and effective as the predicate Bose SoundControl Hearing Aid. The Sonova ADCS1/ADC1 hearing aids have the same intended use and similar

indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Sonova ADCS1/ADC1 hearing aids and its predicate device raise no different questions of safety and effectiveness when the Sonova ADCS/ADC1 is compared to the predicate device. Therefore, the Sonova ADCS1/ADC1 hearing aids are substantially equivalent to the Bose SoundControl Hearing Aid.