October 26, 2023

% Kyle Rose
CEO, Rook Quality Systems
Rook Quality Systems, Inc.
1155 Mount Vernon Highway, Suite 800
Dunwoody, Georgia 30338

Re: K231550
Trade/Device Name: Sontro® OTC Hearing Aids (AI)
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: September 26, 2023
Received: September 27, 2023

Dear Kyle Rose:

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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,

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:

See PRA Statement below.

510(k) Number *(if known)*
K2311550

Device Name
Sontro® OTC Hearing Aids

Indications for Use *(Describe)*

The Soundwave Hearing Sontro® Self-Fitting OTC Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care professional.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510 K Summary
K231550

Preparation Date: September 21, 2023

Applicant Name and Address

Company Name: Soundwave Hearing, LLC
Address: 619 Enterprise Drive, Suite #205
Oak Brook, IL 60523

Official Contact: Anthony Florek
President & Founder, Soundwave Hearing, LLC
Telephone: 708-205-7998
Email: aflorek@hearsoundwave.com

Representative/Consultant

Company: Rook Quality Systems
Address: 1155 Mount Vernon Hwy, Suite 800
Dunwoody, GA 30338

Contact: Kyle Rose
Telephone: 404-717-9358
Email: kyle.rose@rookqs.com

Current Device Information

Trade/Proprietary Name	Sontro® Self-Fitting OTC Hearing Aids
Common Device Name	Self-Fitting Wireless Air-Conduction Hearing Aid, Over-the-Counter
Classification Name	Self-Fitting Wireless Air-Conduction Hearing Aid, Over-the-Counter
Regulation Number	21 CFR 874.3325
Product Code(s)	QUH
Classification	Class II
Review Panel	Ear, Nose, and Throat Devices
Predicate Device	Bose SoundControl Hearing Aid (K211008)
Use	Over-the-Counter (OTC)

1. Device Description

Per 21 CFR 874.3325, a self-fitting wireless air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing. It incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy, enabling users to independently derive and customize their hearing aid fitting and settings. This is an over-the-counter hearing aid.

The Soundwave Hearing, Sontro® OTC (over-the-counter) Hearing Aids are self-fitting wireless air conduction hearing aids consisting of the hardware and software: the device uses the otoTune® app and accessories supplied in the carton. Each hearing aid in the pair functions and interacts with the otoTune® app independently and as a system.

A disposable size 312 zinc-air battery powers the hearing aids. The hearing aids incorporate microphones for audio input, and sound is delivered to the ear via a receiver in the canal that can be coupled with ear domes. The hearing aids are controlled via onboard button controls and wirelessly via the otoTune® app (iOS and Android). The controls allow the user to configure parameters, settings, and listening modes.

2. Intended Use

The Soundwave Hearing Sontro® Self-Fitting OTC Hearing Aids are intended to amplify sounds for use by individuals 18 years and older with perceived mild to moderate hearing impairment. The device is intended for over-the-counter sale and use without the assistance of a hearing care professional.

3. Indications for Use

The Soundwave Hearing Sontro® Self-Fitting OTC Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care professional.

4. Device Information

Per 21 CFR 874.3325, a self-fitting wireless air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing. It incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy, enabling users to independently derive and customize their hearing aid fitting and settings. Self-fitting wireless air-conduction hearing aids are Class II medical devices. The Self-Fitting hearing aids incorporate microphones for audio input, and sound is delivered to the ear via a receiver that can be coupled with domes. Self-fitting hearing aids are controlled via button controls and wirelessly via the smart hearing app (iOS and Android). The controls allow users to adjust the volume setting and customize the hearing mode program.

5. Self-Selection Labeling

Self-selection labeling has been included in the Sontro Self-Fitting OTC Hearing Aid's IFU to mitigate the risk of improper self-selection. Summarized, it addresses:

- A warning against the use of people younger than 18 years of age.
- Identifying criteria that indicate the user should see a hearing professional.
- Identifying situations where Sontro Self-Fitting OTC Hearing Aids may help you hear better.
- Identifying situations in which Sontro Self-Fitting OTC Hearing Aids may not be suitable for the user.
- Informing the user that the Sontro Self-Fitting OTC Hearing Aids will not restore normal hearing.
- Informing the user that it is good health practice to have hearing loss evaluated by an appropriate healthcare professional.

6. Special Controls

The Sontro Self-Fitting OTC Hearing Aids conform to the special controls stated in 21 CFR 874.3325. Soundwave has satisfied these requirements through:

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

7. Comparison of Technological Characteristics

The subject (Sontro Self-Fitting OTC Hearing Aid) and the predicate (Bose SoundControl Hearing Aid) are self-fit hearing aids. The predicate device is considered direct-to-consumer since it was cleared before the finalization of the OTC Hearing Aid Rule; the subject device is an over-the-counter hearing aid. Both the predicate and subject devices are indicated for individuals 18 and older with perceived mild to moderate hearing impairment. The same fundamental technology is present in both the predicate and subject hearing aids to allow the user to control and customize the device to the user's hearing needs.

Both devices contain the same technological characteristics:

- Self-Fit Hearing Aid
- Bluetooth
- On Device Controls

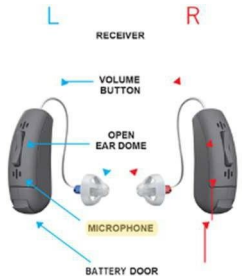
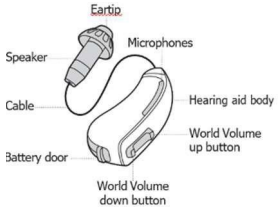
- A traditional receiver-in-the-canal (RIC) style form factor
- Replaceable 312 Battery
- Software App
- Software Platform Compatibility (iOS, Android)

Substantial Equivalence Technological Comparison Summary:

Table 1 Soundwave Hearing conducted a comprehensive equivalency technological comparison between the Sontro® Self-Fitting OTC Hearing Aids and the predicate device (K211008) to facilitate substantial equivalence.

Topic	**Subject Device** (Sontro® Self- Fitting OTC Hearing Aid)	**Predicate Device** (Bose SoundControl Hearing Aid)	**Discussion of Similarities and Differences**
Fitting	Self-Fit Apply personalized gain settings based on user in-situ test. Utilizes the validated NAL-NL2 fitting algorithm.	Self-Fit Loudness and Fine-Tuning. Utilizes a proprietary fitting algorithm.	**Similarities:** Both the predicate and subject devices use proprietary software to program the user's hearing needs to the devices. This self-fitting is done after assessing the user's hearing loss has been assessed by the software. **Differences:** The subject has three patents for self-fitting, which are used in the software applying personalized gain settings based on a user in-situ test and utilizing the validated NAL-NL2 fitting algorithm, personalizing the hearing threshold to the user's unique requirements for hearing amplification. ~~There are no pre-suite hearing thresholds for the software to choose from.~~ The Predicate utilizes a proprietary fitting algorithm, fitting one of several programs that best match the user's hearing threshold with loudness and fine-tuning by the user. NAL-NL2 is widely used by hearing professionals. Clinical and non-clinical testing supports the subject device’s equivalence to the predicate despite technological differences. Clinical and non-clinical testing performed are detailed in this summary.

Intended user Population	18+ Years Old	18+ Years Old	**The same:** The subject and predicate are intended for an 18+ population. This is the intended population requirement in the OTC hearing Aid Rule.
Indications for Use	The Soundwave Hearing Sontro® Self-Fitting OTC Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care professional.	The Bose SoundControl Hearing Aids are intended to amplify sound for adults 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 preprogramming or hearing test is necessary. The device is intended for direct-to-consumer sales without the assistance of a hearing care professional.	**Similar:** The subject Indications for Use is similar to the predicate, with the appropriate adjustments in accordance with the OTC Hearing Aid Final Rule.

Technology	Wireless, self-fitting air-conduction hearing aid	Wireless, self-fitting air-conduction hearing aid	**The same:** The technology between the subject and predicate is the same. The predicate and subject use (RIC) Receiver in the canal technology.
Housing	Behind the ear hearing aid housing. Speakers (receiver) and domes that insert into each ear separate left and right ear devices with user-control push buttons on each unit. 	Behind the ear hearing aid housing. Speakers (receiver) and domes that insert into each ear separate left and right ear devices with user-control push buttons on each unit. 	**Similarities:** The subject and predicate design are similar; they are BTE with receivers and domes that insert into each ear with separate left and right ear devices with user control push buttons on each unit. **Differences:** The shapes of the subject and predicate device housings are slightly different in design. The design differences were tested with a Usability study. Participants were asked questions relating to the physical appearance and comfort of the subject device, with a passing result once responses were evaluated.

Dimensions	Overall, without cable: 27.2 mm long (height) 13.2 mm wide (depth) X 7.8 mm thick (width)	Overall, with cable: 33 mm long x 23 mm wide x 18 mm thick	**Similarities:** The subject and the predicate design are similar; they are both BTE with receivers and domes that insert into each ear with separate left and right ear devices with user control push buttons on each unit. **Differences:** The shapes of the subject and predicate device housings are slightly different in design. The design differences were tested with a Usability study. Participants were asked questions relating to the physical appearance and comfort of the subject device, with a passing result once responses were evaluated.
Expected Service Life	2 years	2 years	**The same:** The expected service life between the subject and predicate is the same.

On Device Controls	Yes	Yes	**Similarities:** The subject and the predicate design are similar, with user-control push buttons on each unit. **Differences:** The subject's shape and predicate device controls differ slightly in design. The design differences were tested with a Usability study. Participants were asked questions relating to the modes and settings of the subject device, with a passing result once responses were evaluated.

Bluetooth	2.4 GHz	2.4 GHz	**The Same:** The Bluetooth connection between the subject and predicate is the same.
Wireless communication	Wireless communication with handheld device via Bluetooth	Wireless communication with handheld device via Bluetooth	**The Same:** The wireless communication between the device and the handheld device (software) is the same between the subject and predicate.
Wireless coexistence	The Sontro® OTC Hearing Aid uses standard 2.4GHz Classic Bluetooth and Bluetooth Low Energy (BLE) standards to communicate between the hearing aid and the user's Bluetooth-enabled device. From the risk assessment, the temporary loss of Bluetooth communication from interfering RF signals is appropriately considered a negligible risk, and according to AAMI TIR 69, wireless coexistence testing is not required. Note that the	The Bose BMD-0012 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	**The Same:** The wireless coexistence between the device and the handheld device (software) is the same between the subject and predicate. Both use 2.4GHz classic Bluetooth Low Energy (BLE) standards to communicate between the hearing aid and the user's Bluetooth-enabled device.

		is not required. Note that the	

	interruption of device control from the App would be similar to when the user is separated from their Bluetooth-enabled device.	interruption of device control from the App would be similar to when the user is separated from their Bluetooth-enabled device.	
Wireless user control functions via mobile app	<u>Volume Control Modes</u> Quiet - Omnidirectional mic Noise - Adaptive mic Entertainment - Fixed Forward mic Left/Right independent control.	<u>Volume Control Modes</u> Focused, Conversation, Outdoors, Music, Television <u>Mic Control</u> Everywhere, Front Left/Right Balance	**Similarities:** Both the subject and predicate software have the ability for the user to control: Volume, modes, and two microphones. The subject and the predicate devices allow for omnidirectional and speech-focus speech options. Omnidirectional and speech-focused options, both devices work within the same 120-degree focus. **Differences:** Subject device modes, microphones, and left/right balance differ in technological function and naming.

	The Sontro® OTC Hearing Aids use two microphones on the device, which allow for directionality. This directionality operates specifically in the three modes of operation. When the device is in Quiet Mode, the microphones work omni-directional or 360 degrees. While in Entertainment Mode, the	The Bose Predicate device has two microphones on the device, which, during use, may be configured by the user to be Everywhere (360 degrees) or in Front (fixed 120 degrees forward) direction of operation.	The additional functionality of the left/right balance of the predicate device does not raise questions of safety or effectiveness for the device. The added Adaptive directionality of the subject device does not raise questions about the safety or effectiveness of the device. Clinical and non-clinical data from a usability study and data from a clinical validation study support substantial equivalence. Additionally, a usability study was performed where participants were asked questions regarding the mode and settings, with a passing result once the results were evaluated.

	Microphones work in a fixed forward direction with a spread of 120 degrees. While in Noise Mode, the microphones work in a forward cone of 120 degrees, but the focus is towards the loudest human speech, called Adaptive Directionality.		
Demonstrate that the hearing Aid device initiates Bluetooth pairing and Bluetooth control functionality	Pairing and control with the paired mobile device.	Pairing and control with the paired mobile device.	**The Same:** Both the subject and predicate devices use Bluetooth capabilities to pair the devices with the software on the handheld device.
Battery	Hearing Aid with a single replaceable 312 zinc-air cell 1.5V, 4 day, 14hr/day battery coin cell	Hearing Aid with a single replaceable 312 zinc-air cell 1.5V, 4 day, 14hr/day battery coin cell	**The Same:** Both the subject and the predicate use a single replaceable 312 zinc-air 1.5V, 4day, 14hr/day battery, coin cell

Battery Life	Up to four days assuming 14hr day usage, depending on the brand and age of batteries	Up to four days assuming 14hr day usage, depending on the brand and age of batteries	**The Same:** Both the subject and the predicate use a single replaceable 312 zinc-air 1.5V, 4day, 14hr/day battery, coin cell

Microphones	During use, the earbuds' microphone may be configured by the user in the following modes: Quiet mode (Omnidirectional 360- degrees degree), Entertainment mode (Fixed Directionality 120-degree Speech focused), or Noise Mode (Adaptive Directionality 120-degree)	During use, the earbuds' microphone may be configured by the user in the following modes: Everywhere mode (Omnidirectional 360-degree) or Front mode (Fixed Directionality 120-degree Speech focused).	**Similarities:** The subject and predicate devices allow omnidirectional 360-degree and speech-focus 120-degree options. **Differences:** The subject device supports an additional adaptive directional 120-degree noise mode that allows the earbuds to determine the most suitable directionality for the microphones for the given environment, dynamically changing the directional pattern to reduce the loudest sounds from the rear. The added automatic selection of directionality does not raise different questions of safety or effectiveness. Nonclinical data from a usability study and data from a clinical validation study support substantial equivalence.
Device Control	On-Device user controls: - Volume up/down - Mode change - Bluetooth Pairing - Clearing out hearing aid setting	On-Device user controls: - Volume up/down - Mode change - Bluetooth Pairing - Clearing out hearing aid setting	**The Same:** Both the subject and the predicate use on-device user controls of a rocker switch that allows for the following: volume up/down, mode change, Bluetooth pairing, and clearing out the hearing aid setting.

Compression	16-channel wideband dynamic range compression	12-channel wideband dynamic range compression	**Similarities:** The subject and the predicate use wideband dynamic range compression **Differences:** The subject uses 16 channels, and the predicate uses 12 channels The 4 additional channels on the subject device are added into the base, mid, and treble and offer similar spectral tilt as the predicate device. The channels are equal divisions of the frequency spectrum from 200 Hz to 8000 Hz. Both the predicate and Sontro® Self-Fitting OTC Hearing Aids share the same spectrum. However, the predicate divides this spectrum into 12 sections (channels) of 650 Hz each, and the subject device divides the spectrum into 16 sections (channels) or 488 Hz. Each channel can be amplified to meet the needs of the user with hearing loss within a channel. The 4 additional channels do not raise different questions of safety or effectiveness.
Noise Reduction	Active noise reduction. Impact noise control.	Active noise reduction. Impact noise control.	**The Same:** The subject and the predicate use active noise reduction with impact noise control.
Feedback Cancellation	Feedback canceller.	Feedback canceller.	**The Same:** The subject and the predicate use a feedback canceller.

Mobile app	Compatible with iOS and Android.	Compatible with iOS and Android.	**The Same:** The subject and the predicate are compatible with iOS and Android.
Telephony	No	No	**The Same:** The subject and the predicate do not use telephony.
Streaming	No	No	**The Same:** The subject and the predicate do not use streaming.
Active Noise Reduction	No	No	**The Same:** The subject and the predicate do not use active noise reduction.
Comparison of Subject Modes and Predicate Modes: Quiet vs. Everywhere, microphones pickup 360 Degree sound; Entertainment vs Front mode, microphones pickup fixed forward sound and Noise mode, microphones pickup dynamic forward sound.			
Omnidirectional 360 degree	Quiet Mode	Everywhere Mode	**Similarities:** The subject's Quiet mode, which allows for 360-degree sound for pickup around the head of the user, is similar to the predicates Everywhere mode. **Differences:** The subject calls this Quiet Mode, and the predicate calls this Everywhere Mode.

Speech Focus 120 degree Fixed Directionality	Entertainment Mode	Front Mode	**Similarities:** The subject's Entertainment mode allows for 120-degree forward sound pickup while reducing the sound behind the user, similar to the predicate's Front mode. **Differences:** The subject calls this Entertainment Mode, and the predicate calls this Front Mode.
Speech Focus 120 degree Adaptive Directionality	Noise Mode	N/A	**Similarities:** Noise mode is not available on the predicate. **Differences:** Noise Mode also allows 120 degrees of sound pick up, similar to the subject's Entertainment mode. However, the sound pickup will move to a person speaking without the users being required to move their heads in that direction. The Subject's Noise mode benefits the user, making interacting with a group more comfortable rather than swiveling their head to face each person speaking as is required by the predicate device that does not have a Noise mode. The subject offers two modes of directionality that the user can choose from. There is no adverse effect of a choice between two vs. one of the predicate devices. Research and studies show the constant increase of adaptive directionality in bilateral hearing aids and the benefit to the user.

Conclusion Technological Comparison

As seen in the comparison table, the subject device and the predicate device have the same design principles and similar design features and performance specifications. The differences in technological characteristics between the subject device, Sontro® Self-Fitting OTC Hearing Aid, and the predicate device (K21108) do not raise different questions of safety and effectiveness. No identified hazard requires additional benefit versus risk analysis supporting substantial equivalence.

8. Substantial Equivalence to Predicate Device

Soundwave Hearing submits the following information to demonstrate that the Sontro® OTC Self-Fitting Hearing Aid is substantially equivalent to the following legally marketed predicate device:

510(k) Number	Predicate Device Name / Manufacturer
K211008	Bose SoundControl Hearing Aid / Bose

The Sontro® Self-Fitting OTC Hearing Aids were evaluated through Clinical and Non-Clinical Performance Testing to demonstrate the substantial equivalence to the predicate device as described in (K211008)

The subject device has the same intended use and similar technological characteristics to the device cleared in K211008.

9. Clinical Data:

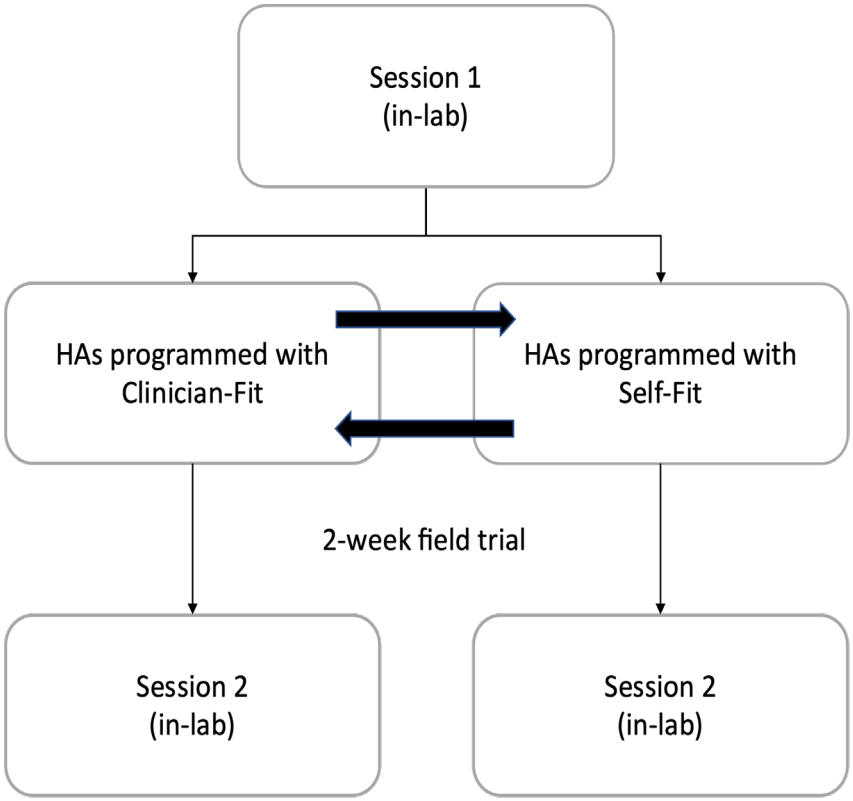
For the in-lab session, the primary effectiveness endpoint was assessed by the differences in acoustical real-ear aided response (REAR), a gold-standard measure for the acoustic function of hearing devices for the study population. This endpoint will assess differences between the mean values after two replications of the SELF-FIT method (reliability) and between the SELF-FIT and CLINIC-FIT methods (validity or effectiveness).

For the wear-time trial, the primary outcome measure is a widely used clinical self-report measure of benefit (Abbreviated Profile of Hearing Aid Benefit, APHAB). The APHAB is also a gold-standard, validated assessment of hearing aid benefits relevant to the study population.

Secondary effectiveness endpoints for the laboratory and field trial components were assessed by a standardized measure of speech communication in noise, the QuickSIN test. This is a widely used clinical measure of an adult's ability to understand speech in noise and is closely tied to the wearer's primary complaint of difficulty communicating in noise.

Overall, the study's success was defined by meeting all primary endpoints for the devices' reliability, effectiveness, and safety and the self-fitting process in this study's laboratory and field trial components. Effectiveness outcomes from the SELF-FIT process were equivalent to those of the CLINIC-FIT method in the in-lab session and non-inferior to CLINIC-FIT in the wear-time trial for the study to be considered successful.

Study Flow:



Participants/ Demographics

Twenty-nine patients enrolled in the study, 13 men and 16 women. Seventeen subjects withdrew due to poor compliance or personal reasons. The age of the enrolled patients ranged from 31 to 75 years, on average 58.9 ± 11.7.

Table 3

	Total	age_min	age_max	age_avg	age_std
Female	16	31	75	60.5	11.6
Male	13	36	70	56.3	11.9
Female + Male	29	31	75	58.9	11.7

by Ethnicity		N	(%)
	White / Caucasian	23	79.4
	Hispanic	0	0
	Hispanic / Black	0	0
	Black / African American	3	10.3
	Asian	3	10.3
	Total	29	100

Study Endpoints

Primary Effectiveness Endpoints

For the validation component of the immediate in-lab session comparisons, Real-Ear Aided Response (REAR) was measured using both an audiology-best-practices (professional) hearing aid fitting (CLINIC-FIT) and a self-fitting method (SELF-FIT).

- Success criterion is defined as SELF-FIT REAR is equivalent to CLINIC-FIT NAL/NL2 prescription REAR targets based on the average real-ear aided response at 500, 1000, 2000, and 4000 Hz with non-inferiority margins at +/- 5 dB (-5 dB ≤ CLINIC-FIT REAR – SELF-FIT REAR ≤ 5 dB).

Real-Ear Aided Response (REAR) was measured twice (A, B) using the SELF-FIT method for the reliability component of the immediate in-lab session comparisons.

- The success criterion is the four-frequency average REAR for SELF-FIT B is equivalent to the REAR for SELF-FIT A based on the average real-ear aided response at 500, 1000, 2000, and 4000 Hz with non-inferiority margins at +/-5 dB (-5 dB ≤ SELF-FIT A – SELF-FIT B ≤ 5 dB).

For the wear-time field trial, the APHAB was measured following an audiology best-practices hearing aid fitting (CLINIC-FIT) and a self-fitting method (SELF-FIT).

- Success criterion is defined as SELF-FIT APHAB global score is non-inferior to CLINIC-FIT APHAB global scores following completion of the wear-time field trial with a non-inferiority margin of ≤8.4 (CLINIC-FIT $APHAB_{global}$ - SELF-FIT $APHAB_{global}$ ≤ 8.4).

Secondary Effectiveness Endpoints

For the validation component of the immediate in-lab session comparison, aided QuickSIN performance was compared between SELF-FIT and CLINIC-FIT.

- The success criterion is the SELF-FIT QuickSIN speech-recognition threshold in noise (signal-to-noise ratio, SNR-loss) is equivalent to that of CLINIC-FIT with a non-inferiority margin at -1.5 dB (-1.5 dB ≤ CLINIC-FIT - SELF_FIT).

For the reliability component of the immediate in-lab session comparison, QuickSIN performance was measured twice (A, B) using the corresponding SELF-FIT method to assess test-retest reliability.

- The success criterion is that QuickSIN thresholds are equivalent for SELF-FIT A and B with non-inferiority margins of ±/-1.5 dB (-1.5 dB ≤ SELF-FIT A – SELF-FIT B ≤ 1.5 dB).

success

For the wear-time field trial, QuickSIN performance was compared between SELF-FIT and CLINIC-FIT after the trial.

- Success criterion is defined as SELF-FIT QuickSIN SNR equivalent to CLINIC-FIT QuickSIN SNR following the wear-time field trial completion with a non-inferiority margin at -1.5 dB (-1.5 dB ≤ CLINIC-FIT QuickSIN – SELF-FIT QuickSIN).

Real-Ear Aided Response (REAR) was measured and compared between the initial FIT device and the same device after the trial for the validation component of wear-time field trial comparisons.

- The success criterion is four-frequency average REAR for FINAL-FIT is equivalent to the REAR for AFTERTRIAL-FIT based on the average real-ear aided response at 500, 1000, 2000, and 4000 Hz with non-inferiority margins at +/-5 dB (-5 dB ≤ AFTERTRIAL_FIT REAR – FINAL-FIT REAR ≤ 5 dB).

Study Conclusions:

Table 4

N=29 patients		endpoints		NI-criterion		average	95%CI upper bound	95%CI lower bound	NI established
REAR	left and right ear together	primary endpoint 1	effectiveness	95% CI lower bound > -5dB 95% CI upper bound < 5dB	CF-(SFA+SFB)/2	0.17	0.78	-0.44	YES
			reliability		SFA-SFB	-0.07	0.73	-0.88	YES
		secondary endpoint 4	reliability		SF(Session1)-SF(Session2)	-0.22	0.42	-0.87	YES
APHAB	GLB	primary endpoint 2	effectiveness	95% CI upper bound < 8.4	CF - SF	1.93	8.21	-4.35	YES
QickSIN	session 1	secondary endpoint 1	effectiveness	95% CI lower bound > -1.5 dB	QSIN CF-(QSIN SFA+QSIN SFB)/2	-0.38	0.18	-0.94	YES
		secondary endpoint 2	reliability	95% CI lower bound > -1.5 dB	QSIN SFA-QSIN SFB	0.28	1.03	-0.48	YES
	session 2	secondary endpoint 3	effectiveness	95% CI lower bound > -1.5 dB	avg(QSIN CF)-avg(QSIN SF)	-0.06	1.36	-1.47	YES

For all 95% confidence interval calculations, the family-wise rate of making a type-I error was controlled. The Bonferroni method was applied. The significance level was adjusted by the number of observations.

For the primary endpoint: In-lab session 1 compares Real-Ear Aided Response (REAR) SELF-FIT REAR with the CLINIC-FIT NAL/NL2 on the average REAR 500, 1000, 2000 and 4000 Hz.

Analysis results:

Table 4 shows the average of the REAR differences between CLINIC-FIT and SELF-FIT (CLINIC_FIT - SELF-FIT). Results are shown for all ears, left ears, and right ears. The point estimate is 0.17 for all ears (left and right combined). The 95% confidence interval for the difference in both ears is (-0.44, 0.78). The non-inferiority margins are at -5 dB and 5 dB.

Conclusion:

The point estimate shows that the average of the differences CLINIC-Fit REAR – SLEF-FIT REAR is within -5 dB and 5 dB. Non-inferiority is demonstrated.

For the primary endpoint: in-lab session 1 compares Real-Ear Aided Response (REAR) SELF-FIT A with SELF-FIT B on the average REAR at 500, 1000, 2000, and 4000 Hz.

Analysis results:

Table 1 shows the averaged differences of the REAR after SELF-FIT-A and SELF-FIT-B. Results are shown for all ears. The point estimate is 0.07 (both ears combined). The 95% confidence interval for the difference in both ears is (-0.88, 0.73). The non-inferiority margins are -5 dB and 5 dB.

Conclusion:

Using all ears, SELF-FIT procedure trial A and trial B lead to similar outcomes. Non-inferiority is demonstrated.

For the primary endpoint: wear-time field trial session 2 compares the APHAB CLINIC-FIT with SELF-FIT.

Analysis results:

Table 4 shows the averaged differences for the $APAHB_{global}$ benefits after two fitting procedures. The point estimate of the effect is 1.93. The 95% confidence interval is (-4.35, 8.21). The non-inferiority margin is 8.4.

Conclusion:

The point estimate favors hearing aid benefits after the CLINIC-FIT procedure. Non-inferiority is demonstrated for the in-lab APAHAB SELF-FIT condition when compared with the CLINIC-FIT condition.

For the secondary endpoint: in-lab session 1 compares QuickSIN SELF-FIT with CLINIC-FIT.

Analysis results:

Table 4 shows the averaged differences in Signal-to-Noise (SNR) loss in dB, which were obtained with the QuickSIN test. Results for the two hearing aid fitting procedures are compared, CLINIC-FIT and SELF-FIT. The point estimate of the effect is -0.38. The 95% confidence intervals for the difference is (-0.94, 0.18). The non-inferiority margin is -1.5 dB.

Conclusion:

The point estimate favors the CLINIC-FIT procedure. Non-inferiority is demonstrated for the in-lab SELF-FIT Procedure.

For the secondary endpoint: in-lab session 1 compares QuickSIN SELF-FIT A with SELF-FIT B.

Analysis results:

Table 4 shows the averaged differences in Signal-to-Noise (SNR) loss in dB, which were obtained with the QuickSIN test. Results for two hearing aid fitting procedure are compared, SELF-FIT A and SELF-FIT B. The point estimate of the effect is 0.28, favoring the SELF-FIT B procedure. The 95% confidence intervals for the difference is (-0.48, 1.03). The non-inferiority margin is -1.5.

Conclusion:

SELF-FIT procedure trial A and trial B lead to similar outcomes. Non-inferiority is demonstrated.

For the secondary endpoint: wear-time field trial session 2 compares QuickSIN SELF-FIT with QuickSIN CLINIC-FIT.

Analysis results:

Table 4 shows the difference of the average SNR-loss in dB for the wear-time field trial. Results for the CLINIC-FIT and SELF-FIT are compared. The point estimate of the effect is -0.6, favoring the CLINIC-FIT procedure. The 95% confidence intervals for the difference were (-1.47, 1.36). The non-inferiority margin is -1.5.

Conclusion:

The lower bound of the 95% confidence interval, -1.47, is larger than -1.5 dB. Non-inferiority is demonstrated for the SELF-FIT procedure.

For the secondary endpoint: wear-time field trial session 2 compares REAR initial FIT device with the same FIT device after the trial.

Analysis results:

Table 4 shows the averaged differences in REAR between initial FIT device versus the same FIT device after the trial. The point estimate of the effect is -0.22 (both ears combined). The 95% confidence interval for the difference in both ears was (-0.87, 0.42). The non-inferiority margins are -5 dB and 5dB.

Conclusion:

After the wear-time field session 2, the REAR outcomes after the Initial FIT procedure are similar to the REAR outcomes using the FIT after the trial. Non-inferiority is demonstrated.

Safety Evaluation:

All participants were free from ear infections, pain or discomfort, acute or chronic dizziness, and no sudden onset or rapid deterioration of tinnitus in one or both ears during baseline screening and wearing hearing aids. No adverse events were reported during the clinical trial.

Clinical Data Study Conclusion

The clinical data from this study demonstrates the effectiveness of the self-fitting strategy and satisfies the special controls for the self-fitting hearing aid regulation. Participants experienced non-inferior outcomes with self-fitting compared to clinician fitting of the subject device.

10. Non-Clinical Performance Testing

Technological Similarities

The Sontro® Self-Fitting OTC Hearing Aids and predicate device (K211008) share the following technological similarities:

Table 5 Soundwave Hearing conducted Non-Clinical Performance Testing on the Sontro® Self-Fitting OTC Hearing Aids to provide a reasonable assurance of the safety and effectiveness of the device as compared to the predicate device (K211008).

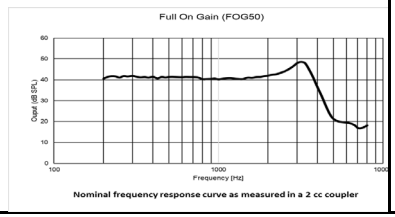
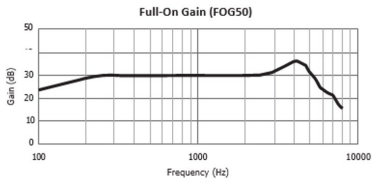
Test Specifications	**Test**	**Result**
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 **ANSI/AAMI ES60601-1**:2005 & A1:2012 **IEC 60601-2-66** 2019 Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems	Electrical Safety: Rating (clause 4.11) Determination of Accessible parts (clause 5.9.2) Legibility of markings (cl. 7.1.2) Durability of Markings (cl 7.1.3) Leakage/Auxiliary current (cl.8. 7, IEC 60601-2-66, 201.8.7.2.8) Cleaning 11.6.1 (wax removal) Detachment /Mechanical pull test IEC 60601-2-66 CL. 201.9.2.102 Drop test IEC 60601-2-66 201.15.3	Conforms, Pass
IEC 60601-1-2 2014 + A1:2020 Medical electrical equipment part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - requirements and tests	Electromagnetic Compatibility, EMC	Conforms, Pass
CISPR-11- 2015 + A1:2016 A2:2019 Industrial, scientific, and medical equipment-Radio-frequency disturbances characteristics-Limits and methods of measurements	RF Radiated Emissions	Conforms, Pass
Test description for CISPR Results ANSI C63.10:2013	**Requirements:**	**Result**
6dB Bandwidth 99% Bandwidth Output Power Power Spectral Density Low Band Edge Duty Cycle Correction Factor EIRP	FCC 15C 15.247 ISED RSS-247	All Tests - Confirm/Pass
Spurious Radiated Emissions High Band Edge		
IEC 60601	**Electromagnetic Immunity**	**Result**

IEC 61000-4-2	Electrostatic Discharge (ESD)	Conforms/ Pass
IEC 61000-4-3	Radiated Immunity Test	Conforms/ Pass
IEC 61000-4-8	Magnetic Field Immunity	Conforms/ Pass
IEC 60118-7	Electro acoustical testing	Conforms/ Pass
IEC 61000-4-6 - ***The subject devices are battery-operated and do not have a connection via cable.	Required for devices connected to a cable, does not apply	N/A
ANSI S3.22	**Electro acoustical**	**Result**
Special Control 2 ANSI/CTA 2051-2017 and underlying ANSI S3.22-2014	Electroacoustic Characteristics	Conforms/ Pass
ANSI/ASA S3.22-2014 (6.8)	Frequency Response (Gain)	Conforms/ Pass
ANSI/CTA 2051:2017(4.1) with underlying test method ANSI S3.22:2014 (6.9)	Electro Acoustic -frequency Response Bandwidth	Conforms/ Pass
ANSI S3.22:2014 (6.2)	Acoustic Output dB Sound Pressure Level at input 90 db Sound pressure Level (OSPL 90)	Conforms/ Pass
ANSI S3.22:2014 (6.2)	Maximum Acoustic Output Sound Pressure Level Input 90dB SPL (Max OSPL90)	Conforms/ Pass
ANSI S3.22:2014 (6.11)	Harmonic Distortion (Output Distortion)	Conforms/ Pass
ANSI S3.22:2014 (6.12)	Equivalent Input Noise (EIN)	Conforms/ Pass
ANSI/CTA 2051:2017 (4.8)	Latency	Conforms/ Pass
ANSI S3.22:2014 (6.3)	High Frequency Average Output Sound Pressure Level (HFA OSPL 90)	Conforms/ Pass

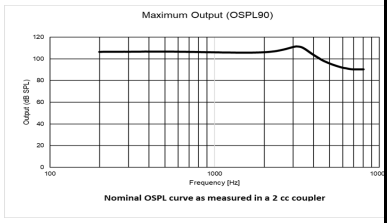
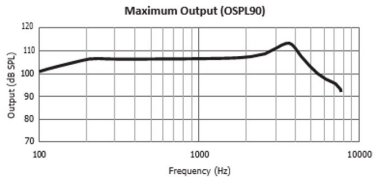
ANSI S3.22:2014 (6.5)	High Frequency Average Full on Gain (HFA FOG)	Conforms/ Pass
ANSI S3.22:2014 (6.7)	Reference Test Gain (RTG)	Conforms/ Pass
ANSI/CTA 2051:2017 (4.10 – 4.17)	Fixed or Level-Dependent Frequency Equalization Level - Dependent Gain/Compression Noise reduction Signal to Noise Ratio Enhancement Feedback Control Personalization Coupling to the Ear Wireless Connectivity	Conforms/ Pass
Performance Data: Subject Device Designed in Conformance with Standards		
ISO 14971:2019	Application of Risk management to Medical Devices	Conforms
IEC 62366-1:2015	Software- Medical Device Software- Software Life-Cycle Processes	Conforms
IEC 62304:2006+ A1:2015	Software- Medical Device Software- Software Life-Cycle Processes	Conforms

ANSI/ ASA S3.22 2014 Measurements Comparison

Table 6 To prove substantial equivalence with the predicate device, Soundwave Hearing evaluated the ANSI S3.22 data set from the predicate (K211008) devices' ANSI/ASA 3.22 measurements to establish substantial equivalence in acoustic performance.

Test Standard / Method	**Test Purpose Description**	**Sontro® Self-Fitting OTC Hearing Aid (Subject Device)**	**Bose Hearing Aid (Predicate Device)**	**Discussion**
Special Control 2 ANSI/CTA 2051-2017 and underlying ANSI S3.22-2014	Electroacoustic Characteristics	Frequency range: 200-8000 Hz. Maximum output (90 dB SPL input): 112 dB SPL. Equivalent noise input level: 25dB HFA Full-On-Gain (50 dB SPL input): 42 dB Latency: <1ms THD@500Hz: 0.9% THD@ 800Hz: 01.0% THD@1600Hz: 0.4% Per ANSI S3.22-2014 – 2cc coupler High Frequency Average (HFA) per ANSI S3.22-2014 definition, the average of gain or SPL in decibels at 1000, 1600 and 2500 Hz.	Frequency range: 200-8000 Hz. Maximum output (90 dB SPL input): 113 dB SPL. Equivalent noise input level: 23dB HFA Full-On-Gain (50 dB SPL input): 30 dB Latency: 5.5ms THD: 0.5% Per ANSI S3.22-2014 – 2cc coupler High Frequency Average (HFA) per ANSI S3.22-2014 definition, the average of gain or SPL in decibels at 1000, 1600 and 2500 Hz.	**Similar to** the predicate and suitable for the intended user: ANSI/CTA 2051-2017 uses measurement methods and 2cc coupler from ANSI S3-22, and as such, the frequency range, maximum output & equivalent noise input level can be compared directly to the predicate device. Total harmonic distortion (THD) and latency meet the requirements of ANSI/CTA 2051-2017, with requirements of <5% and <15 ms, respectively. Direct comparison to the predicate device is not possible as the performance of the predicate device on these parameters is not publicly available. The latency and total harmonic distortion meet the requirements in ANSI/CTA 2051-2017. The subject device is also compliant with 21CFR800.30 requirements for OTC hearing aids.
ANSI/ASA S3.22- 2014 (6.8)	Frequency Response (Gain)	Reference Figure 1 	Reference Figure 2 	**Similar to** predicate and suitable for the intended user. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Specification of hearing aid characteristic and testing both in accordance with ANSI S3.22- 2014 supports substantial equivalence.

				The subject device is also compliant with 21CFR800.30 requirements for OTC hearing aids.
ANSI/CTA	Electro Acoustic -	200Hz to 8000Hz	200Hz to 8000Hz	**The Same** as the predicate

2051:2017(4.1) with underlying test method ANSI S3.22:2014 (6.9)	frequency Response Bandwidth			
ANSI S3.22:2014 (6.2)	Acoustic Output dB Sound Pressure Level at input 90 dB Sound pressure Level (OSPL 90)	Reference Figure 3  	Reference Figure 4  	**Similar to** the predicate and suitable for the intended user. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Specification of hearing aid characteristics and testing both in accordance with ANSI S3.22, support substantial equivalence.
ANSI S3.22:2014 (6.2)	Maximum Acoustic Output Sound Pressure Level Input 90dB SPL (Max OSPL90)	112 dB SPL which is less than or equal to 120 dB SPL	113 dB which is less than or equal to 120 dB SPL.	**Similar to** the predicate The subject is 112dB predicate is 113dB both are less than or equal to 120dB SPL The subject device is also compliant with 21CFR800.30 requirements for OTC hearing aids.
ANSI S3.22:2014 (6.11)	Harmonic Distortion (Output Distortion)	Total Harmonic Distortion THX 500 Hz 0.9% THX 800 Hz 1.0% THX 1600 Hz 0.4%	Less than or equal to 0.5%	**Similar to** the predicate. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study support substantial equivalence. The subject device is also compliant with 21CFR800.30 requirements for OTC hearing aids.
ANSI S3.22:2014 (6.12) per K211008	Equivalent Input Noise (EIN)	25 dB SPL which is less than or equal to 32 dB SPL	23 dB SPL which is less than or equal to 32 dB SPL	**Similar to** the predicate. 2 Db SPL difference between the subject and the predicate. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study support substantial equivalence. The subject device is also compliant with 21CFR800.30 requirements for OTC hearing aids.

ANSI/CTA 2051:2017 (4.8) per K211008	Latency	<1ms	5.5 ms	**Similar to** the predicate. **Difference**: The subject's lower number <1ms vs 5ms may enhance the user experience; however, the difference between 1ms and 5ms may not be able to be perceived by the user. The subject device is also compliant with 21CFR800.30 requirements for OTC hearing aids.
ANSI S3.22:2014	High Frequency	107 dB SPL	106 dB SPL	**Similar to** the predicate. Adequate for

(6.3) per K211008	Average Output Sound Pressure Level (HFA OSPL 90)			fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study support substantial equivalence.
ANSI S3.22:2014 (6.5) per K211008	High Frequency Average Full on Gain (HFA FOG)	42 dB	30 dB	**Similar to** the predicate, adequate for fitting mild to moderate. hearing loss as prescribed by NAL-NL2. **Difference** While the subject FOG value of 42 dB is greater than the predicate's 30 dB this ensures that our device has the ability to meet the same gain requirements once fitted as the predicate even though the user may not need more amplification prescribed by NAL-NL2. Data from a clinical validation study supported substantial equivalence.
ANSI S3.22:2014 (6.7) per K211008	Reference Test Gain (RTG)	27 dB	29 dB	**Similar to** the predicate. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study supports substantial equivalence.
ANSI/CTA 2051:2017 (4.10 – 4.17) per K211008	Fixed or Level-Dependent Frequency Equalization	level-dependent frequency equalization that is adjusted via user controls.	utilize 12-channel wide dynamic range compression to make conversation easier without making loud sounds too loud.	**Similar to** the predicate. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study supports substantial equivalence.
	Level-Dependent Gain/Compression	utilize 16-channel wide dynamic range compression to make conversation easier without making loud sounds too loud.	utilize 12-channel wide dynamic range compression to make conversation easier without making loud sounds too loud.	**Similar to** the predicate. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study supports substantial equivalence.

	Noise Reduction	make steady noises (like vacuum cleaners, air conditioners, etc.) less loud.	make steady noises (like vacuum cleaners, air conditioners, etc.) less loud.	**The Same** as the predicate.
	Signal-to-Noise Ratio Enhancement	have user-selectable directional microphones to emphasize sounds from in front, making conversations in noisy places easier.	have user-selectable directional microphones to emphasize sounds from in front, making conversations in noisy places easier.	**The Same** as the predicate.
	Feedback Control	reduce feedback (whistling).	reduce feedback (whistling).	**The Same** as the predicate.
	Personalization	are self-tuned by the user either via an app on a smart device (phone or tablet) Individual hearing thresholds are determined via an in situ hearing test to personalize the amplification settings.	are self-tuned by the user either via an app on a smart device (phone or tablet) or by using the on-device controls. Individual hearing thresholds are not required to personalize the amplification settings.	**Similar to** the predicate. Adequate for fitting mild to moderate hearing loss as prescribed by NAL-NL2. Data from a clinical validation study supports substantial equivalence.
	Coupling to the Ear	have a user-adjustable fit for greater comfort and better sound quality. The ear tip is a soft, conical, open, or closed tip that rests deep in the ear canal.	have a user-adjustable fit for greater comfort and better sound quality. The ear tip is a soft, conical, open, or closed tip that rests deep in the ear canal.	**The Same** as the predicate.
	Wireless Connectivity	use Bluetooth technology to control the hearing aids via a paired smart device.	use Bluetooth technology to control the hearing aids via a paired smart device.	**The Same** as the predicate.

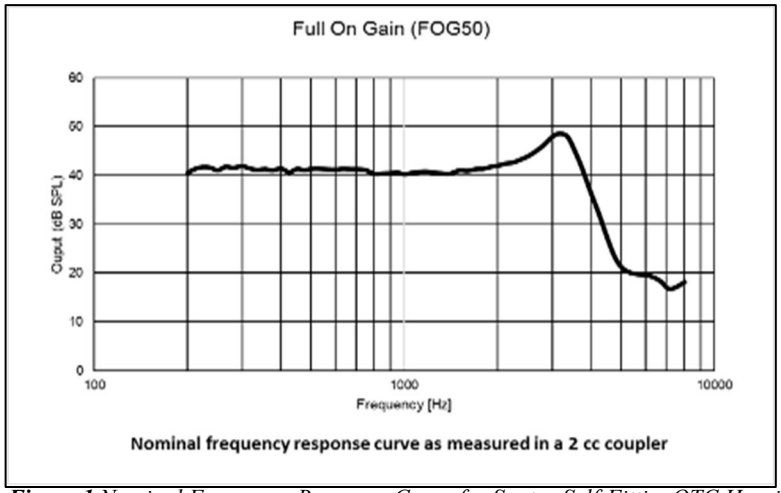


Figure 1 *Nominal Frequency Response Curve for Sontro Self-FittingOTC Hearing Aids Full on Gain (FOG50)*

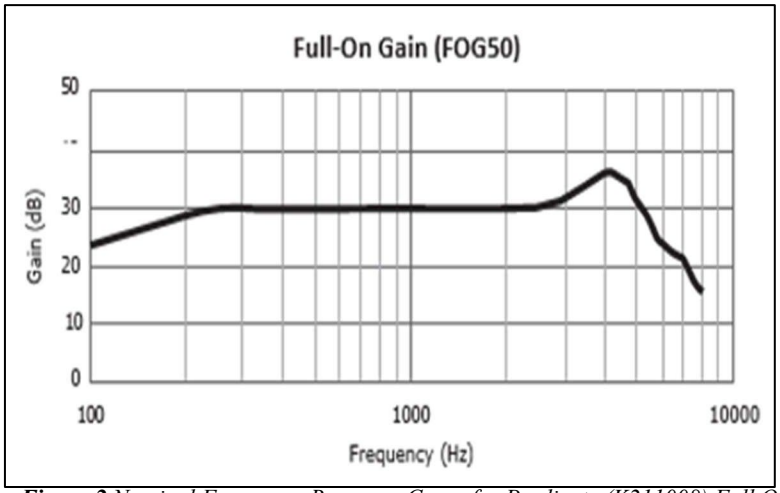


Figure 2 *Nominal Frequency Response Curve for Predicate (K211008) Full On Gain (FOG50)*

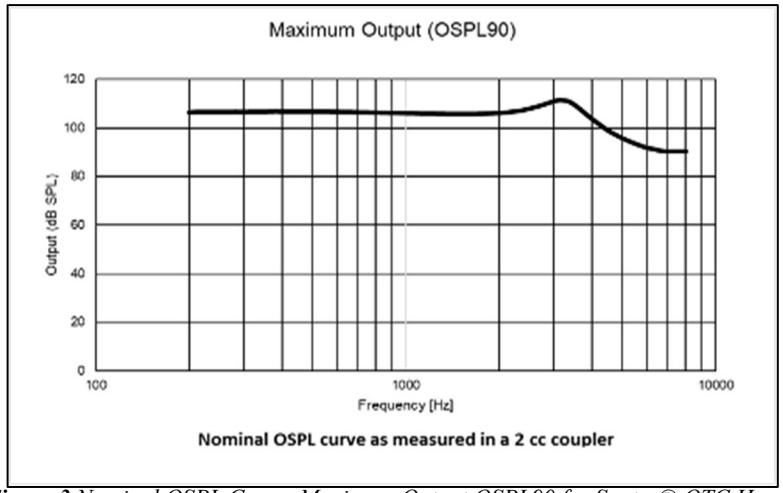


Figure 3 *Nominal OSPL Curve, Maximum Output OSPL90 for Sontro® OTC Hearing Aid*

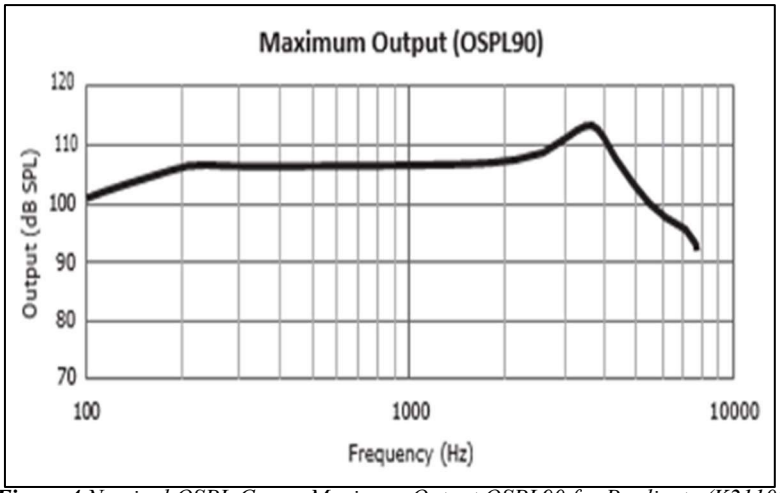


Figure 4 *Nominal OSPL Curve, Maximum Output OSPL90 for Predicate (K211008)*

Usability Testing

Soundwave conducted a human factors validation test of the Sontro® Self-Fitting OTC Hearing Aids. The usability testing included 17 untrained participants representing the intended user population (individuals 18 years of age or older with perceived mild to moderate hearing impairment).

The test was performed in the participant's homes, representing the intended use environment of the Soundwave Hearing Sontro® OTC Hearing Aids. Each participant performed hands-on use scenarios and knowledge tasks with the Soundwave Hearing Sontro Self-Fitting OTC Hearing Aids, including the otoTune® app, packaging, accessories, and user documentation. All interaction points between the user and the device were tested to validate user needs and the operation of each device component and user interface as a whole.

After the use scenarios and knowledge tasks, the online tests asked open-ended questions to collect participants' subjective assessments of the use safety and usability by the moderator. The Zoom interviews (during covid) focused on topics of particular interest, ease of use of the otoTune app to customize the Sontro Self-Fitting Hearing Aids, and the validation of the user's improved hearing with the Sontro Self-Fitting Hearing Aids. Users were asked to assess their ability to hear more clearly in noisy environments and assess making adjustments to volume, the equalizer, and noise reduction settings in the Control screen.

Data for the usability test was collected through observational data by 1 Zoom call per participant to observe the participant set up the device. Knowledge task data, 2 follow-up user interviews to assess the ability of the user to operate the device with the user manual, quick start guide, labeling on the device itself, and changing and replacing ear domes, wax guards, and receivers. The interviewer recorded this observational and knowledge task data during the testing to include use problems and use errors.

Participants were given four online tests to record and evaluate the knowledge tasks, points of interaction and operational device components. The results of the human factors validation testing were analyzed qualitatively to determine if the design of the device (or the labeling or user training) needs to be modified to reduce the use-related risks to acceptable levels.

Usability Testing indicates that the subject device and app are able to be used correctly for the intended user, uses, and environment.

11. Non-Inferiority Conclusion

The Sontro® Self-Fitting OTC Hearing Aids have the same intended use and fundamental technology as the predicate, Bose SoundControl Hearing Aid (K211008). Similarly, as its predicate, the Sontro® OTC Hearing Aids are a user-fitted wireless air-conduction hearing aid

intended for use by individuals 18 years or older with perceived mild to moderate hearing impairment.

The differences in technological characteristics between the subject device, Sontro Self-Fitting OTC Hearing Aid, and the predicate device (K21108) do not raise different questions of how safe and effective they are under specified use conditions. No identified hazard requires additional benefit versus risk analysis supporting non-inferiority.

Clinical testing results indicate that the data support our hypothesis that the device's self-fit procedure is non-inferior to the predicate for the hearing aid fitting in a clinical setting for patients with mild to moderate hearing loss. The clinical study showed:

> Real-Ear Aided Responses compare after the self-fit procedure and the fitting of the hearing aid by a certified audiologist. Non-inferiority for the differences of the fitting procedures has been established.
>
> The global APHAB scores and the outcomes of the QuickSIN test show that Sontro Self-Fitting OTC Hearing Aids provide benefits in hearing for mild to moderate hearing-impaired individuals. Non-inferiority for the differences of the fitting procedures has been established.
>
> The outcomes of the QuickSIN test are similar after the self-fit procedure and the fitting of the hearing aid by a certified audiologist. Non-inferiority for the differences of the fitting procedures has been established.
>
> No adverse incidences during the use of the hearing aids have been reported during the study.
>
> Sontro Self-Fitting OTC Hearing Aids, as well as the predicate device, are safe and provide use benefits (effective). The self-fit procedure for both devices is non-inferior to the fitting by a certified audiologist.

Non-clinical performance testing based on the ANSI/ASA S3.22 standards demonstrated the Sontro Self-Fitting OTC Hearing Aids are acoustically comparable to the predicate device(K211008). Non-clinical testing has been conducted to confirm that variations in both form factor and software do not compromise the established safety and effectiveness benchmarks set by the predicate device (K211008).

The subject device Sontro Self-Fitting OTC Hearing Aids conformed to/passed all the non-clinical tests and standard evaluations for Electrical Safety, Electromagnetic Compatibility, CISPR RF Radiated Emissions, CISPR ANSI C63.10:2013, Electromagnetic Immunity, Electro acoustical per ANSI S-322 and was designed in conformance with ISO 14971:2019, IEC 62366-1:2015, IEC 62304:2006+ A1:2015.

Results from the usability test indicated that Soundwave Hearing's Sontro® Self-Fitting OTC Hearing Aids Hearing and otoTune app are able to be used correctly by the intended users under the anticipated condition of use. No identified hazard requires additional benefit versus risk analysis in support of non-inferiority for the Sontro Self-Fitting OTC Hearing Aids.

In summary, the combined evidence from technology equivalence assessments, clinical testing, non-clinical performance testing, EMC testing, and results from usability testing supports the conclusion that the Sontro Self-Fitting OTC Hearing Aids are non-inferior to the predicate device (K211008).

Conclusion

The Sontro® Self-Fitting OTC Hearing Aids are substantially equivalent in intended use and fundamental scientific technology to the Bose SoundControl Hearing Aids (K211008). The Sontro Self-Fitting OTC Hearing Aids are considered as safe and effective as the predicate device for their intended use when used in accordance with the otoTune® app and the Instructions for Use as Self-Fitting OTC Hearing Aids, QUH.