October 17, 2023

Intricon Corporation
David Akbari
Senior Medical Science, Clinical and Regulatory Affairs Liaison
1260 Red Fox Road
Arden Hills, Minnesota 55112

Re: K223911
Trade/Device Name: Lumen 155-SF
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QUH
Dated: August 31, 2023
Received: September 15, 2023

Dear Dr. Akbari:

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

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.

Submission Number *(if known)*

Device Name

Lumen 155-SF

Indications for Use *(Describe)*

The Lumen® 155-SF self-fitting, wireless air conduction 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 over-the-counter sales without the assistance of a hearing health 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.

510K SUMMARY FOR DEVICE

The 510(k) Summary is provided on the following pages as required by 21 CFR 807.92(c).

1. SUBMITTER INFORMATION

Company Name:	Intricon Inc.
Company Address:	1260 Red Fox Road Arden Hills, MN 55112
Company Contact:	David Akbari, Senior Medical Science, Clinical and Regulatory Affairs Liaison
Email:	dakbari@intricon.com
Phone/Fax:	651-587-8347

2. DEVICE IDENTIFICATION

Trade Name:	Lumen 155-SF Self-Fitting Hearing Aids with Sentibo Application
Generic Device Name:	Hearing Aid
Classification Name:	Self-Fitting, Air-Conduction Hearing Aid, Over the Counter
Regulation Class:	Class II
Product Code:	QUH
Assigned K-number:	K223911
Regulation Number:	21 CFR 874.3325
Panel:	Ear, Nose and Throat Devices

3. PREDICATE AND REFERENCE DEVICES

Predicate Device:
Nuheara IQbuds™ 2 PRO (K221064)
Reference Devices:
Bose Sound Control (K211008)
Bose De Novo (DEN180026)
The predicate and reference device(s) have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

Per 21 CFR 874.3325 a self-fitting wireless air conduction hearing aid is a wearable sound amplifying device that is intended to compensate for impaired hearing and incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users

to independently derive and customize their hearing aid fitting and settings. Self-fitting wireless air conduction hearing aids are class II medical devices.

Device Characteristics

The Lumen 155-SF self-fitting hearing aid(s) with Sentibo application is a self-fitting wireless air conduction Behind-The-Ear (BTE) hearing aid consisting of the Intricon hardware and Sentibo software to be used on an Apple mobile device (mobile device not included) including wired lightning connector Apple EarPods for the assessment (not included) designed for a single user. The Sentibo app is available only on iOS. The Lumen 155-SF self-fitting OTC hearing aid(s) with Sentibo application is a behind the ear device that includes self-adjustable coupling by means of a slim tube and ear tip/open dome. The hearing aids can be fine-tuned by the user or remotely at the request of the user via the use of QR codes. Once the hearing aids are switched on, the software (Sentibo app) is required for the initial set-up, which is done via the smart phone and requires Apple EarPods with lightning connector to complete (not included). The Sentibo self-fitting software allows the consumer to self-select a hearing profile from a list of options by listening to digitized speech embedded in the software while scrolling through the hearing profiles in real-time listening through the Apple EarPods. After the setting is selected, the settings can be transferred from the smart phone to the hearing aid directly, though direct audio streaming from the smart phone to the hearing aid is unsupported with the Lumen 155-SF firmware. All Sentibo settings are stored in the application itself, and no internet service is required to perform the self-fitting. The Sentibo application provides 24 predefined options. At the conclusion of the assessment, the software will program hearing aids wirelessly and the user will wear the hearing aids per normal use. The smartphone app will function as a software accessory, allowing the user to make minor adjustments to the hearing aids. The hearing aid is intended to be used with the Sentibo App and to be worn and removed daily by the end user.

Materials of Use

The hearing aid makes long term/permanent contact with the skin in and around the ear. The body of the hearing aid rests on the outer shell of the ear (behind the ear) and is coupled to a dome via a slim tube that is worn inside of the ear canal. The materials used in the construction of the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application are biocompatible presenting no biological risk; thus, the requirements of ISO 10993-1 have been met.

Key Performance Specifications

The hearing aids are used with a replaceable, disposable, 1.45V, size 312 zinc air battery. The digital signal processing on the hearing aids allows for the following features to be adjustable: wide dynamic range compression, 16 frequency bands, noise reduction, feedback cancellation, wind noise suppression, low level expansion and microphone arrays (adaptive and fixed microphone directionality).

5. INTENDED USE/INDICATIONS FOR USE

The Lumen® 155-SF self-fitting, wireless air conduction 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 over-the-counter sales without the assistance of a hearing care professional.

6. LABELING

Self-Selection Labeling has been included in the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application product label and Instructions for Use (IFU) to mitigate the risk of improper self-selection. Summarized, it addresses the following:

- Identifying situations in which the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application may help users hear better;
- Identifying situations in which the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application may not be right for users.
- Identifying criteria that indicate users should see a hearing professional.
- Informing users that the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application will not restore normal hearing.
- Informing users that it is good health practice to have hearing loss evaluated by a licensed healthcare professional.

7. SPECIAL CONTROLS

The Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application conforms to the special controls stated in 21 CFR 874.3325.
These requirements are satisfied through following:

- Clinical Performance Validation
- Non-clinical Performance Testing
- Summative Usability/Human Factors Validation
- Labeling

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application has the same intended use and fundamental technology as the predicate, Nuheara IQbuds 2 PRO (K221064). In the same manner as its predicate, the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application is a user-fitted wireless air-conduction hearing aid intended for over-the-counter use by individuals 18 years or older with perceived mild to moderate hearing impairment. The same fundamental scientific technology is present in both hearing aids to allow the user to control and customize the device to the user's hearing needs. The Sentibo application adds a unique element to the assessment by requiring the use of wired Apple EarPods with lightning connector terminus to perform the assessment, after which settings from the simulated model are transmitted to the hearing aid for use. The use of the Apple EarPods to perform the self-assessment and to transfer settings to the hearing aid has been electro-acoustically verified and performs similarly to the predicate device in terms of its measured acoustic output. The subject device is similar to the predicate in product design, dimension, use of Bluetooth technology and utilizing materials of high standard. The principles of operation of the subject device is explained as equivalent to the predicate. The subject device has no known biocompatibility issues, no known effect on the environment, or to other devices. At a high level, the subject and predicate devices are based on the following technological elements:

- Self-fitting Air Conduction Hearing Aids
- Wireless Application via Bluetooth
- On device controls
- App (Sentibo Application)

- Software Platform Compatibility (iOS)

While both subject and predicate device both have the following elements at a high level, various differences in implementation exist such as the use of rechargeable versus replaceable batteries, and the device embodiment (behind the ear versus in the ear). These differences, where present, do not materially affect the safety or effectiveness of the device.

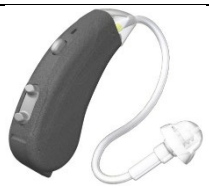
- Batteries (Replaceable, disposable, 1.45 Volt, Size 312, Zinc Air, Batteries)
- Behind-The-Ear (BTE)
- Bi-directional Microphones
- User-Adjustable Tube Length Selection
- Different size ear tips
- Feedback Cancellation
- 16 Channel-wide Dynamic Input Compression
- Open Ear Tips in 3 sizes (Small, Medium, Large)
- 16 channel Noise Reduction
- Requires wired Apple EarPods with lightning connector terminus

Any differences between the subject and predicate device have been addressed through testing to a known performance standard. These differences are not significant and do not impact the effectiveness or safety of the subject device.

The intended use and technological characteristics, (e.g., features, parameter settings etc) are similar to the predicate device (Nuheara IQbuds 2 PRO) cited above. The table below summarizes the characteristics of the Lumen 155-SF Hearing Aids in comparison to the predicate and, as applicable, one of the reference devices. The reference device Bose De Novo (DEN180026) serves a reference specific to the self-fitting strategy (i.e., self-administered hearing test and subsequently applied prescription) and clinical trial design, where the Bose Soundcontrol (K211008) is referenced because it uses the same self-fitting strategy as the Bose De Novo and represents a closer physical embodiment match to the subject device in that both are Behind The Ear (BTE) hearing aids. Since the Bose Soundcontrol is a closer physical match to the subject device, this specific reference device is referred to in the following table along with the predicate device as compared to the subject device for the purpose of demonstrating substantial equivalence.

Comparison of Subject and Predicate Devices				
	Subject	**Predicate**	**Reference**	**Discussion of Differences**
Device Trade Name	**Lumen 155-SF**	**Nuheara IQbuds™ 2 PRO**	**Bose Sound Control**	
510k Number	**K223911**	**K221064**	**K211008**	
Product Code	**QUH**	**QUH**	**QDD**	**Same as predicate** The over-the-counter (OTC) version of the self-fitting hearing aid has a different product code

				(QUH) to differentiate it from the direct-to-consumer (DTC) version (QDD) as used in the Bose Soundcontrol (K211008) reference device.
Regulation Number	21 CFR 874.3325	21 CFR 874.3325	21 CFR 874.3325	**Same as predicate**
Regulation Name	Self-fitting air conduction hearing aid	Self-fitting air conduction hearing aid	Self-fitting air conduction hearing aid, prescription	**Same as predicate**
Intended Use	The Lumen 155-SF self-fitting, wireless air conduction hearing aids with Sentibo application are intended to amplify sound for adults 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 over-the-counter sales without the assistance of a hearing care professional.	The Nuheara IQbuds 2 PRO Hearing Aids are intended to amplify sound for individuals with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for over the counter sale and use without the assistance of a hearing care professional.	The Bose Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The device is intended for direct-to-consumer sale and use without the assistance of a hearing care professional.	**Similar to predicate and reference Bose Soundcontrol (K211008)** The clause "no pre-programming or hearing test is necessary" was omitted in the subject device as redundant in the context of a self-fitting hearing aid.
Indications for Use	The Lumen 155-SF 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 pre-programming or hearing test is necessary. The device is intended for over-the-counter sales without the assistance of a	The Nuheara IQbuds 2 PRO self-fitting hearing aids are intended to amplify sound for individuals 18 years and older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. No pre-programming or hearing test is necessary. The	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 pre-programming or hearing test is necessary. The device is intended	**Same as predicate and reference Bose Soundcontrol (K211008)**

	hearing care professional.	device is intended for over-the-counter sale and use without the assistance of a hearing care professional	for over-the-counter sales without the assistance of a hearing care professional.	
Technology (batteries)	**312 zinc-air [non-rechargeable] hearing aid batteries**	Rechargeable Lithium- ion polymer batteries	**312 zinc-air [non-rechargeable] hearing aid batteries**	**Same as reference Bose Soundcontrol (K211008)** Subject device battery is non-rechargeable while the predicate is a rechargeable. The predicate Nuheara IQbuds 2 PRO (K211064) recharges by use of an AC plug adapter and connector to recharge, and cannot be used while charging. The subject device uses disposable zinc-air 312 batteries with drain noted in the ANSI S3.22 standard. The difference in batteries does not introduce new questions of safety as both devices meet the respective performance requirements for battery drain based on the technology used.
Housing	 **Behind-the-ear (BTE)**	 **In-the-ear (ITE)** hearing aid	 **Behind-the-ear (BTE)**	**Same as reference Bose Soundcontrol (K211008)** Although the subject device hearing aid housing is a

	hearing aid housing. Separate left and right ear units (earbuds) with user control push buttons on each unit. **Sold in pairs**	housing. Separate left and right ear units (earbuds) with a separate Ear Tip for each unit. On device, 'Tap Touch' control to streaming audio and use with phone (via Bluetooth) **Sold in pairs**	hearing aid housing. Separate left and right ear units (earbuds) with user control push buttons on each unit. **Sold in pairs**	behind-the-ear style instead of an in-the-ear style, the difference in housing does not raise different questions of safety or effectiveness since both are tested to the same electroacoustic standards (ANSI/ASA S3.22 via reference in ANSI/CTA 2051).
Input signal compression	Multichannel, wide dynamic range compression	Wide dynamic range compression	Multichannel, wide dynamic range compression	**Same as reference Bose Soundcontrol (K211008)** The subject, predicate, and reference devices all feature a form of wide dynamic range compression. The way in which frequency sub-divisions are used by the processing algorithm do not raise different questions of safety or effectiveness since both subject and predicate Nuheara IQbuds 2 PRO (K221064) devices are tested to the same electroacoustic standards.
Microphones	Omnidirectional or Direction modes	Omnidirectional or Direction modes	Omnidirectional or Direction modes	**Same as predicate and reference Bose Soundcontrol (K211008)**
Battery Life	**100 hours** *(312 zinc-air [non-rechargeable] hearing aid batteries)*	Per CTA 2051 (4.1-4.17) Battery life of up to 8 hrs	**56 hours** *Up to 4 days, assuming 14hr day usage.* *(312 zinc-air [non-rechargeable]*	**Same as reference Bose Soundcontrol (K211008)**

			hearing aid batteries)	Battery drain differs between rechargeable and disposable batteries and does not raise any different issues of safety and effectiveness.
Noise Reduction	The Lumen 155-SF features multi-layered adaptive noise reduction with selectable intensity (Low 7 dB, Medium 10 dB, High 13 dB, Max 17 dB)	Hybrid Active Noise Cancellation	Steady state noise reduction	The subject device performs in a similar manner to the predicate Nuheara IQbuds 2 PRO (K221064) and reference device Bose Soundcontrol (K211008) by reducing hearing aid output in response to detected noise signals. The method of detection and amount of gain reduction in response to environmental noise utilize different proprietary methodologies and were considered in context in the clinical data for the subject, predicate, and reference devices. The specific algorithm differences do not raise different issues of safety and effectiveness.
Self-fitting method	User selects their preferred audio settings by listening to a smartphone using Apple lightning connector wired EarPods. Users audition their preferred settings based on predefined set of 24 options.	Device uses a proprietary Ear ID, a validated NAL-NL2 fitting algorithm	Adequate for fitting moderate hearing loss (55 dB HL) as prescribed by NAL-NL2	The predicate Nuheara IQbuds 2 PRO (K221064) device uses the NAL/NL2 self-fitting method which depends on the acquisition of pure tone audiometric thresholds, whereas the

				subject device's functionally similar self-fitting method uses digitized human voice. The subject device's fitting method is adequate for fitting mild to moderate hearing loss, the same as prescribed by NAL-NL2. Sentibo OTC provides 24 predefined options. In the subject device, Apple EarPods are required while they are not required for either predicate Nuheara IQbuds 2 PRO (K221064) or reference devices. The subject device has been measured and validated in-situ to demonstrate that the EarPod presented running speech range is the basis by which the hearing aid also performs when used with its volume control and input-controlled compression. Because the subject device meets the same electroacoustic test standards as the predicate and reference devices, no different questions of safety or effectiveness are introduced despite the technological differences in fitting approach.

Mobile App	Mobile application on a smart device (phone or tablet) with iOS platform	Mobile application on a smart device (phone or tablet) with either iOS or Android platforms	Mobile application on a smart device (phone or tablet) with either iOS or Android platforms	**Similar to Predicate and Reference Device Bose Soundcontrol (K211008)**, except subject device is not compatible with Android platform
Remote firmware updates	Not supported	The subject device via the Nuheara app allows for remote firmware updates to the hearing aids.	The hearing aids update automatically when connected to the Bose Hear app. Follow the app instructions.	**Subject device does not allow for remote firmware updates** While the subject device does not support remote firmware updates and both the predicate Nuheara IQbuds 2 PRO (K221064) and reference device Bose Soundcontrol (K211008) do, the subject, predicate, and reference device all conform to similar wireless recognized consensus standards. Since the subject device does not allow the potential for firmware modification wirelessly, no new questions of safety or effectiveness are introduced.

Electro-Acoustic Characteristics per ANSI/ASA S3.22 and ANSI/CTA 2051:2017 (and ANSI/ASA S3.22 by reference)				
	Subject	**Predicate**	**Reference**	**Discussion of Differences**
Device Trade Name	**Lumen 155-SF**	**Nuheara IQbuds™ 2 PRO**	**Bose Sound Control**	Same as predicate Nuheara IQbuds 2 PRO (K221064) within measurement uncertainty tolerance. The subject, predicate, and reference Bose Soundcontrol (K211008) devices all have programmable latency, and all are less than or equal to 15 ms as specified in ANSI/CTA 2051.
510k Number	**K223911**	**K221064**	**K211008**	
Latency clause 4.8	5.8 ms	5 ms	5.5 ms	
Frequency response	< 200 Hz - 8000 Hz	200 Hz - 8000 Hz	< 200 – 8000 Hz	The subject device meets the requirements, same as the predicate.
Input distortion clause 4.4.2	Less than or equal to 5% (measure is 1.2%)	Less than or equal to 5% (measure is 0.7%)	Less than or equal to 5%	The subject device meets the requirements, same as the predicate.
Equivalent Input Noise (EIN) (Self-generated Noise Levels) Clause 6.12	26.4 dB SPL	28.5 dB SPL	< 23 dB SPL typical, < 27 dB SPL max	The subject device meets the requirements, same as the predicate.
Harmonic Distortion Clause 6.11	<0.5% typical, <1% max	0.2%	< 0.5% typical, < 1% max	The subject device meets the requirements, same as the predicate. The results describing “typical” and “max” are from repeated measures on multiple units in order to confirm the values as it relates

				to the ANSI/ASA S3.22 test for harmonic distortion. The difference between the slim tube embodiment of the subject device and the ITE embodiment of the reference device will result in slightly different values between the units, but both devices meet the same electroacoustic requirements.
Max OSPL90 Clause 6.2	114.4 dB SPL	109.6 dB SPL	113 dB SPL	The subject device meets the requirements, same as the predicate. The subject, predicate Nuheara IQbuds 2 PRO (K221064), and reference device Bose Soundcontrol (K211008) feature output limiting and input-controlled compression and show OSPL90 values that are less than the maximum allowable 117 dB SPL limit.
HFA OSPL90 Clause 6.3	109.6 dB SPL	100.9 dB SPL	106 dB SPL	The subject device meets the requirements, same as the predicate.
HFA FOG Clause 6.5	51 dB	29.4 dB SPL	30 dB	The subject device will provide more amplification for soft sound inputs. No specific gain limit was identified or required in the final OTC rule. While higher than the predicate Nuheara IQbuds 2 PRO (K221064) and reference Bose Soundcontrol

				(K211008) devices, device gain is dependent on the input. Since the subject device features output limiting which is always enabled, no different questions of safety or efficacy are introduced as a result of this difference.
Reference Test Gain (RTG) Clause 6.7	45 dB	24.4 dB SPL	29 dB	The subject device meets the requirements, same as the predicate Nuheara IQbuds 2 PRO (K221064). Reference Test Gain is descriptive only according to ANSI/ASA S3.22. Where differences between the subject device and predicate device exist, no different questions of safety or efficacy are introduced.

9. NON-CLINICAL PERFORMANCE DATA

The subject device was tested for conformity to the following FDA recognized consensus standards applicable to the self-fitting hearing aid for its intended use.

Biocompatibility

- ISO 10993-1 Biological evaluation of medical devices
- ISO 10993-12 Biological evaluation of medical devices
- ISO 10993-5 Biological evaluation of medical devices
- ISO 10993-10 Biological evaluation of medical devices

Electro-Acoustics

- ANSI/ASA S3.22 2014 (R2020) Measurements
- ANSI/CTA 2051 2017

In order to establish substantial equivalence to the predicate device, Intricon evaluated the electroacoustic data as found in the predicate and required under Special Controls for 21 CFR §874.3325. As seen in the Electroacoustic Characteristics per ANSI S3.22 and CTA 2051:2017 table above, the measurement for the specific cited clauses indicates that the Lumen 155-SF hearing aid(s) with Sentibo application are

substantially equivalent in acoustic performance to the predicate device, Nuheara IQbuds 2 PRO (K221064).

10. Electrical Safety, EMC, Battery Safety, Software, and Labeling

Consistent with the predicate device, the Lumen 155-SF Hearing Aid(s) with Sentibo application passed all relevant non-clinical performance testing and biological endpoints, namely cytotoxicity (ISO 10993-05:2009) sensitization, and intracutaneous reactivity (ISO 10993-10:2010). Similarly, software verification and validation, testing to established consensus standards for electrical safety, EMC and battery safety demonstrated mitigation of risks to an acceptable level as well as reasonable assurance of safe and effective device non-clinical performance, consistent with the predicate and reference devices, the Nuheara IQbuds 2 PRO, and the Bose Soundcontrol Hearing Aid, respectively.

Standard	Test Purpose	Result
IEC 60118-13:2016 EMC Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility	To demonstrate hearing aid compliance to the IEC 60118-13 EMC requirements	Pass
BS EN 60601-2-66: 2015 Basic Safety and Essential Performance of Air-Conduction Hearing Aids	To verify that the hearing aid complies with the basic safety and essential performance requirements of the particular standard BS EN 60601-2-66:2015, Medical Electrical Equipment – Part 2-66: Particular Requirements for the Basic Safety and Essential Performance of Hearing Instruments and Hearing Instrument Systems and the general standard, BS EN 60601-1:2006+A1:2013, Medical Electrical Equipment – Part 1: General requirements for Basic Safety and Essential Performance	Pass
BS EN 60601-2-66: 2015 Patient Leakage Current Results for Hearing Aids	To demonstrate conformity with clause 201.8.7 of BS EN 60601-2-66 to assure basic safety and essential performance of the hearing aids.	Pass
IEC 60601-1-2: 2015 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance –	Electromagnetic Compatibility	Pass

Collateral Standard: Electromagnetic disturbances – Requirements and tests		
IEC 60601-1-11 Vibration and Shock Environmental Testing Results for the Lumen 155	To demonstrate the conformity of shock and vibration characteristics of the Lumen 155 air conduction hearing devices as per IEC 60601-1-11.	Pass
FCC & RED Tests - Lumen 155 (L 155) Wireless	To provide evidence that the Lumen 155 wireless hearing instrument platform meets the electromagnetic requirements of the Federal Communications Commission	Pass
AAMI TIR69 Wireless Coexistence Risk Analysis for Air Conduction Hearing Aids	To review the risks associated with Wireless Coexistence for Air Conduction Hearing Aids	Pass
IEEE / ANSI C63.27:2017 – Evaluation of Wireless Coexistence	Bluetooth SIG Compliance	Pass
ANSI C63.19: 2019 – Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids	Radio Frequency Immunity	Pass

Note: Full Non-clinical Performance Testing results, including acceptance criteria and testing performance are reported in the 510(k) submission.

11. USABILITY TESTING AND CLINICAL PERFORMANCE DATA

Usability Testing

In the usability analyses, preliminary analysis along with design changes intended to reduce the identified use-related risks were implemented iteratively throughout the product development process. Analytical methods were used to identify 'critical/essential' tasks.

Fifteen adults (18 yrs. and older) with a perceived mild to moderate hearing loss

were enrolled after passing screening of inclusion/exclusion criteria. Task driven Formative Evaluations followed by an inclusive Summative Evaluation were conducted in a one-on-one quiet, comfortable room fit with two chairs and a table on which the participants could handle the device and a smartphone. Informed Consent was obtained for each participant before enrollment and all sessions were video-taped.

While no tasks were identified that met the criteria for 'critical' there were 3 deemed 'essential' (device is not hearing protection and other warnings/cautions from the User Guide). An independent, trained moderator conducted each session which involved a series of steps for accessing, fitting and then using the hearing aid in simulated use conditions. All participants were scored on status of completion of all steps in each of the tasks. A cross-functional team reviewed outcomes at frequent intervals and addressed changes to be considered to labeling, product packaging, and iterative minor design changes to the user interface to accommodate the user needs. The same cross-functional team reviewed and approved the Summative Evaluation Report. The evaluation provided evidence that the device was safe and effective to operate by the intended user when used in accordance with its intended use.

Overall, the human factors study demonstrated that the usability of the Lumen 155-SF hearing aid(s) with Sentibo application were analyzed, verified, and validated for its intended use and the implemented mitigations for user training and device labeling are adequate.

Clinical Performance

Clinical Performance with the Lumen 155-SF Hearing Aid(s) with Sentibo application were assessed with a multicenter, prospective, randomized, single-blind, parallel-arm study comparing outcomes of two fitting approaches: self-fitting with Sentibo OTC mobile app (Self-fit) or licensed professional fitting (Pro-fit) with the same hearing aid device.

The primary objective of this study was to demonstrate non-inferiority of satisfaction outcomes of participants using the self-fit Sentibo OTC mobile app (Self-fit) when compared to licensed professional-fit (Pro-fit) hearing aids.

The secondary objectives were:

- To evaluate the quality of hearing in typical consumer use.
- To evaluate the participants' perceptions of benefit.
- To assess satisfaction among naïve and experienced users.
- To estimate the rate of device-related adverse events.

The exploratory objectives were:

- To verify the acoustic conditions likely to be present at the eardrum by the hearing aid.
- To validate the acoustic conditions provided by the self-fit app.

Participants included 93 adults self-identified with perceived mild-to-moderate hearing loss. This validation of the Lumen 155-SF with Sentibo self-fitting methodology for the target population (adults with perceived mild to moderate hearing loss) used an assessment approach similar to that of the reference device Bose Soundcontrol Hearing

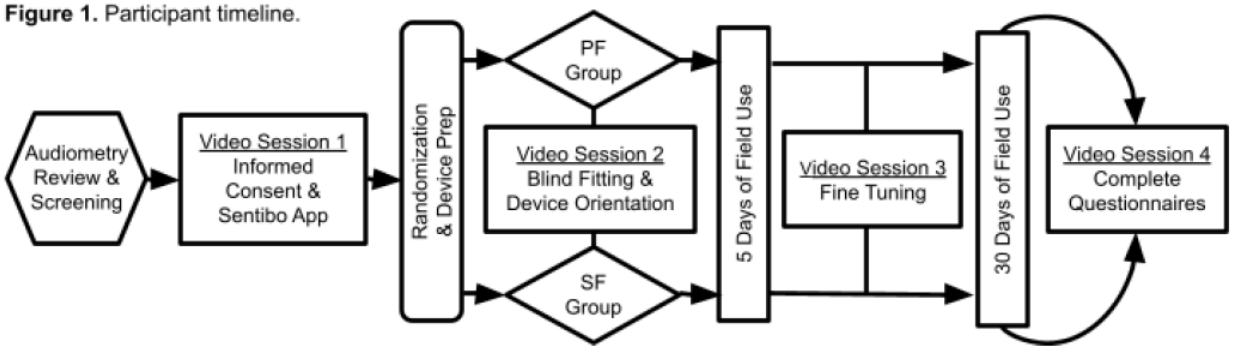
Aid (K211008) by assessing clinical effectiveness *quantitatively* and *qualitatively*. Those measures involved the following described by endpoint objective:

Primary objective assessment. To meet the primary objective of demonstrating non-inferiority of satisfaction outcomes of participants using the self-fit Sentibo OTC mobile app (Self-fit) when compared to licensed professional-fit (Pro-fit) hearing aids, participants completed two 5-point satisfaction scales, one which assessed their satisfaction with their hearing aids' sound quality and one which assessed their satisfaction with the fitting process.

Secondary objective assessment. In addition to rating scales modeled after the reference device, to meet secondary objectives about perceived benefit and quality of hearing, participants completed the Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech, Spatial and Qualities Hearing Scale (SSQ-12). The APHAB assesses a participant's perceived benefit of wearing hearing aids on the ease of communication in a variety of contexts (e.g., background noise, reverberation) and aversiveness to sound. The SSQ-12 asks respondents to consider listening to speech in a variety of contexts that vary in distance, movement, and direction.

Exploratory objective assessment. To meet the exploratory objectives of verifying the acoustic conditions likely to be present at the eardrum by the hearing aid and validating the acoustic conditions provided by the self-fit app, simulated real-ear measures were obtained using a KEMAR manikin to represent the characteristics of the average acoustic response of the head, neck, torso, pinna, and ear canal. A VeriFit 2 real-ear analyzer was used to present acoustic stimuli to the manikin in the free-field condition. Individual participant thresholds were entered in order to generate NAL-NL2 targets, and both pro- and self-fit settings were measured, regardless of group assignment. Hearing aid output was documented for the International Speech Test Stimulus (ISTS) presented at 50 (soft), 65 (mid), and 80 (loud) dB SPL with a Maximum Power Output (MPO) tone sweep at 85 dB SPL. All measurements were obtained at the default volume control level (a level of 0 between +10 and -10 dB from the programmed level). All measures were obtained with input-controlled compression and volume control active and in place.

Figure 1. Participant timeline.



The study was designed to adhere to COVID-19 social distancing needs. The COVID-19 pandemic offered a unique opportunity to study Sentibo under the contact-free conditions for which it is intended. All questionnaires, wellness checks, and communication between the study's audiologists and the participants were administered through appropriate remote means (e.g., video conference calls and email).

Table 1. Study Events and Assessments

	Screening & Baseline	Video Session 1 Sentibo Selection	Video Session 2 First fit	Field Use ~ 5 days	Video Session 3 Fine tuning	Field Use ~ 30 days	Video Session 4 Final	Post Participant Study Exit
Eligibility Assessment	X							
Informed Consent		X						
Point of Enrollment		X						
Randomization		X						
Demographics & Medical Hearing History		X						
Otoscopy Exam Provided	X							
Audiogram Provided	X							
Sentibo Listening & Selection Process Prior to Hearing Aids		X						
Initial Fitting (PF or SF)			X					
Fine Tuning (PF or SF)					X			
Participant Questionnaires (Satisfaction, SSQ-12 and APHAB)							X	
Adverse Event Evaluation			X	X	X	X	X	
Simulated Real-Ear Measures								X
Optional Ongoing Support from Hearing Help Express								X

Ninety-five English speaking adults (one had English as a second language) with self-perceived mild-to-moderate hearing loss were consented and enrolled in the Satisfaction with Self-Fitting Hearing Aid Software Compared to Licensed Professional-Fitting of the Same Hearing Aid Device clinical trial. Three participants departed the study after consenting for reasons not related to the hearing aid or Sentibo fitting strategy. One participant decided not to participate after consenting but did not start the protocol, a second participant was lost to follow-up after the initial hearing aid fitting, and a third participant had an unforeseen death in the family and was not available during their appointments. Therefore, 92 participants provided data for analyses.

All participants were required to provide an audiogram and otoscopic clearance obtained by a licensed professional within 6 months of their consent date. Exclusion criteria included a history of significant middle ear disease, surgical remediation of the ear, and congenital anomaly. The potential participant was excluded if the audiogram indicated a significant discrepancy between self-reported mild-to-moderate hearing loss and the audiological report (e.g., profound hearing loss). The participants were randomly assigned to either the self-fit (Self-fit) or the pro-fit (Pro-fit) group. Tables 2 and 3 present detailed demographic and audiological information for both groups.

Table 2. Demographic data

	Self-Fit	Pro-Fit
Sample Size	45	47
Age (years) mean, s.d.	66.1; 10.1	63.8; 14.4
Female / Male (# participants)	26 / 19	30 / 17
Married / Divorced / Single / Widowed	33 / 7 / 2 / 3	36 / 3 / 5 / 3
Number of people in home (sd)	2.2 (0.8)	2.6 (1.2)
Full Time / Part Time / Retired / Not Employed	15 / 5 / 23 / 2	16 / 7 / 21 / 3
Years of education (sd)	15.4 (2.1)	15.7 (2.1)
# With previous HA experience / # without HA experience	12 / 33	17 / 30
# With > 5 years smartphone experience / # with < 5 years experience	39 / 6	42 / 5
Primary Smartphone OS experience Apple / Android / Both	36 / 5 / 4	35 / 6 / 6

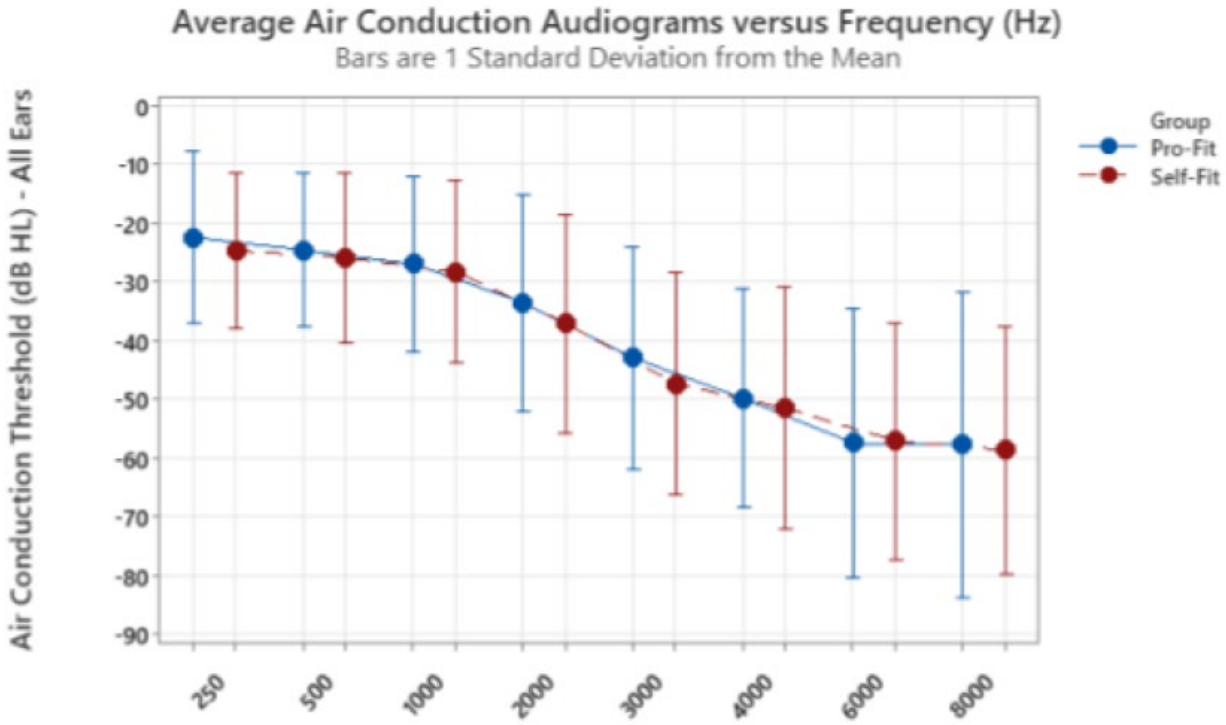
Table 3. Audiological data

	Self-Fit	Pro-Fit
Sample Size	45	47
4F PTA (dBHL; s.d.)	Right Ear=36.0; 14.1 Left Ear=35.7; 13.9	Right Ear=33.5; 13.6 Left Ear=34.0; 14.7
Sensorineural (# participants)	44	42
Mixed* (# participants)	1	5
Asymmetrical (# participants)**	2	6

*Air Bone Gap is >15db at 500Hz, 1000Hz and 2000Hz,
**Average PTA at 500Hz, 1000Hz, 2000Hz and 4000Hz is >15dB between ears

Figure 2 shows the means and standard deviations at each audiometric test frequency for each group. No significant differences were found between groups at any test frequency.

Figure 2. Audiometric Thresholds



Study Results

The primary objective of this study was to demonstrate the noninferiority of outcomes for participants who use new hearing aids that have been programmed with the self-fit Sentibo OTC mobile app (Self-fit) versus hearing aids that have been programmed by an audiologist using commercially available fitting software (Pro-fit). Both Self-fit and Pro-fit groups yielded similar levels of satisfaction for the sound quality of their hearing aids (Figure 3) and with the fitting process (Figure 4).

Figure 3. Responses to the sound quality question.

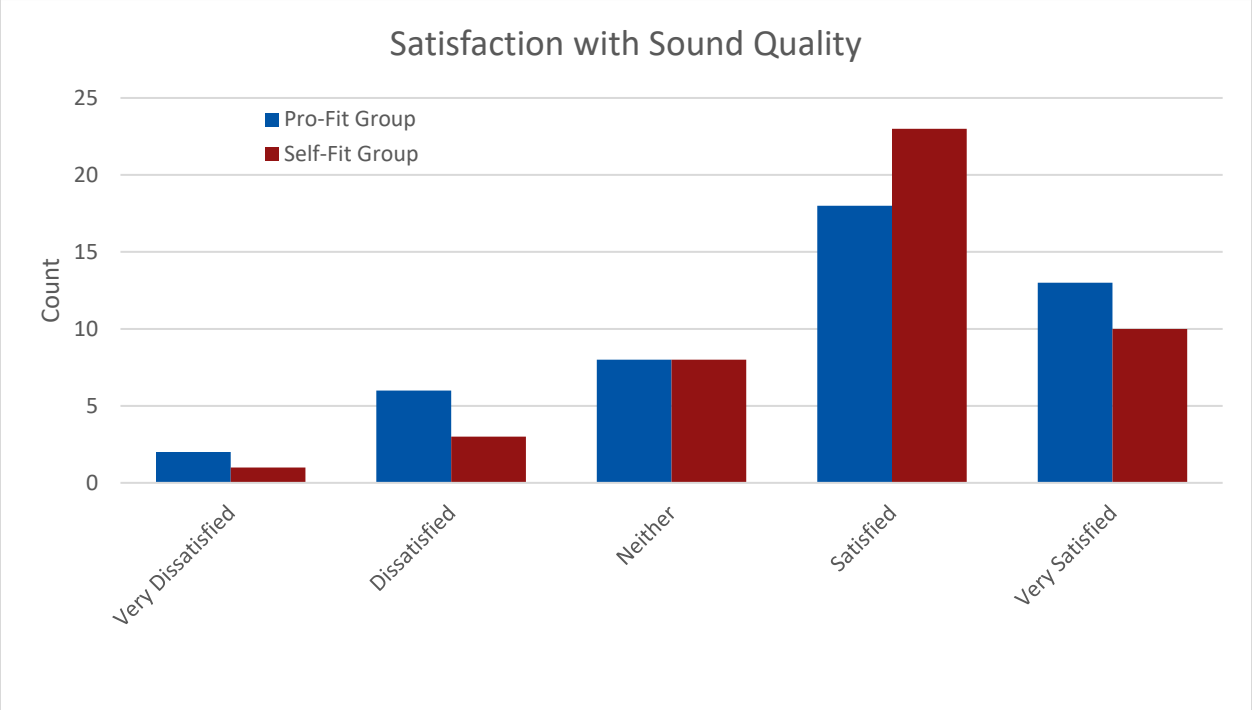
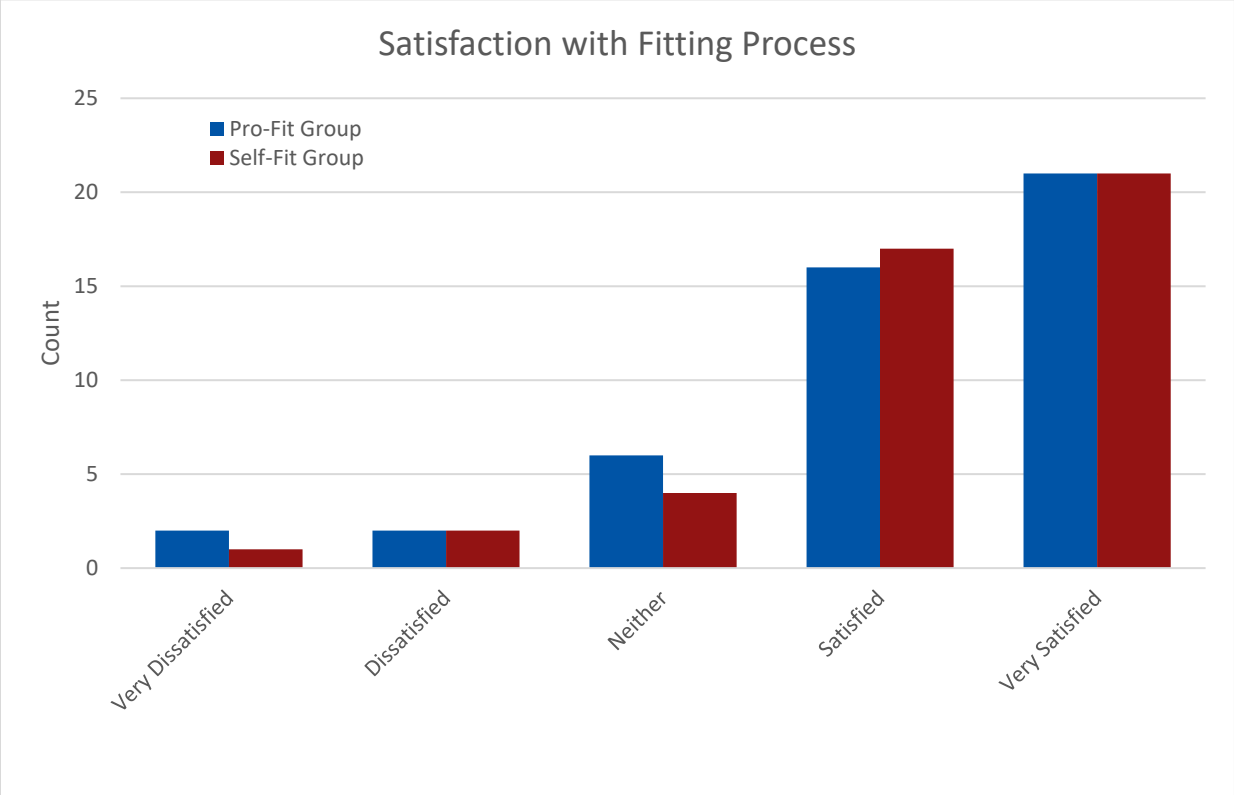


Figure 4. Responses to the fitting process question.



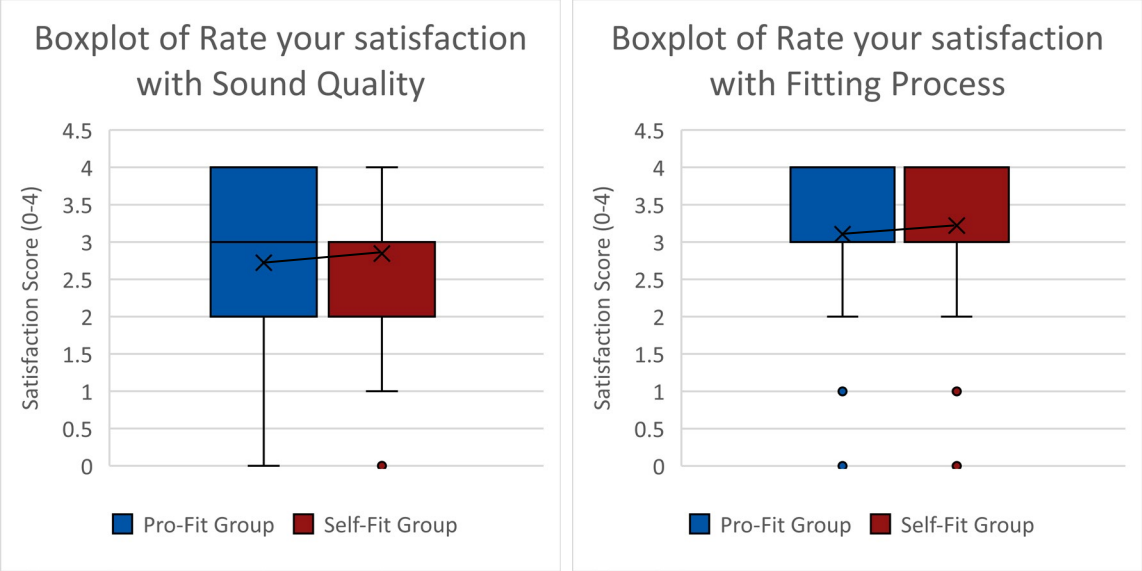
Question 1

- Pro-fit mean of 2.72 (SD=1.14)
- Self-fit mean of 2.84 (SD=0.93**)**

Question 2

- Pro-fit mean of 3.11 (SD=1.07)
- Self-fit mean of 3.22 (SD=0.95)

Figures 5 and **6.** Comparison of the overall scores for the two questions.



The secondary objectives were to evaluate the quality of hearing in typical consumer use, to evaluate the participants' perceptions of benefit, to assess satisfaction among naïve and experienced users, and to estimate the rate of device-adverse events. Results from the SSQ-12 and APHAB appear in Table 4.

Table 4. Test results

	Self-fit Mean (SD, Range)	Pro-fit Mean (SD, Range)
SS Questionnaire #1	2.8 (0.9, 0 - 4)	2.7 (1.1, 0 - 4)
SS Questionnaire #2	3.2 (1.0, 0 - 4)	3.1 (1.1, 0 - 4)
SSQ-12 Benefit Score	6.8 (1.7, 1 - 10)	6.5 (1.5, 3 - 10)
APHAB Global Score	10.0 (17.3, -25 - 50)	12.8 (19.7, -25 - 55)

The SSQ-12 focuses on the listener's perceived ability to perform across twelve different listening environments. The output is an average of all scores that ranged from Not at all (0) to Perfectly (10). The overall mean score for the Self-fit group output scores on the

SSQ-12 were 6.8 (SD=1.7) and for the Pro-fit group, 6.5 (SD=1.5), indicating that the two groups had similar levels of perceived benefit.

The scores on the APHAB are determined by calculating the benefit associated with wearing a hearing aid. Participants evaluate their ability in everyday situations both with and without a hearing aid on a seven-point scale. Benefit scores are calculated as a difference between performance with a hearing aid and performance without an aid. The standard outcome for the APHAB is a global benefit score which provides an index of the benefit a person receives from their hearing aid. The overall mean score for the Self-fit group was 10.0 (SD=17.3) and for the Pro-fit group, 12.8 (SD=19.7), indicating that the two groups had similar levels of perceived benefit.

The exploratory objective of this study was to quantitatively confirm measured sound pressure levels at the ear canal in order to document safety and examine efficacy. As shown in Figure 7 the actual maximum output SPL for the MPO test among all participants in all conditions was 101.3 dB SPL (n=184 ears). Figures 8, 9, and 10 show measured results from the hearing aid in-situ minus the NAL-NL2 targets for both the Pro-fit and Self-fit groups which resulted in similar matches to NAL-NL2 targets by frequency.

Figure 7. Overall Maximum Sound Pressure, Pro-fit and Self-fit groups combined

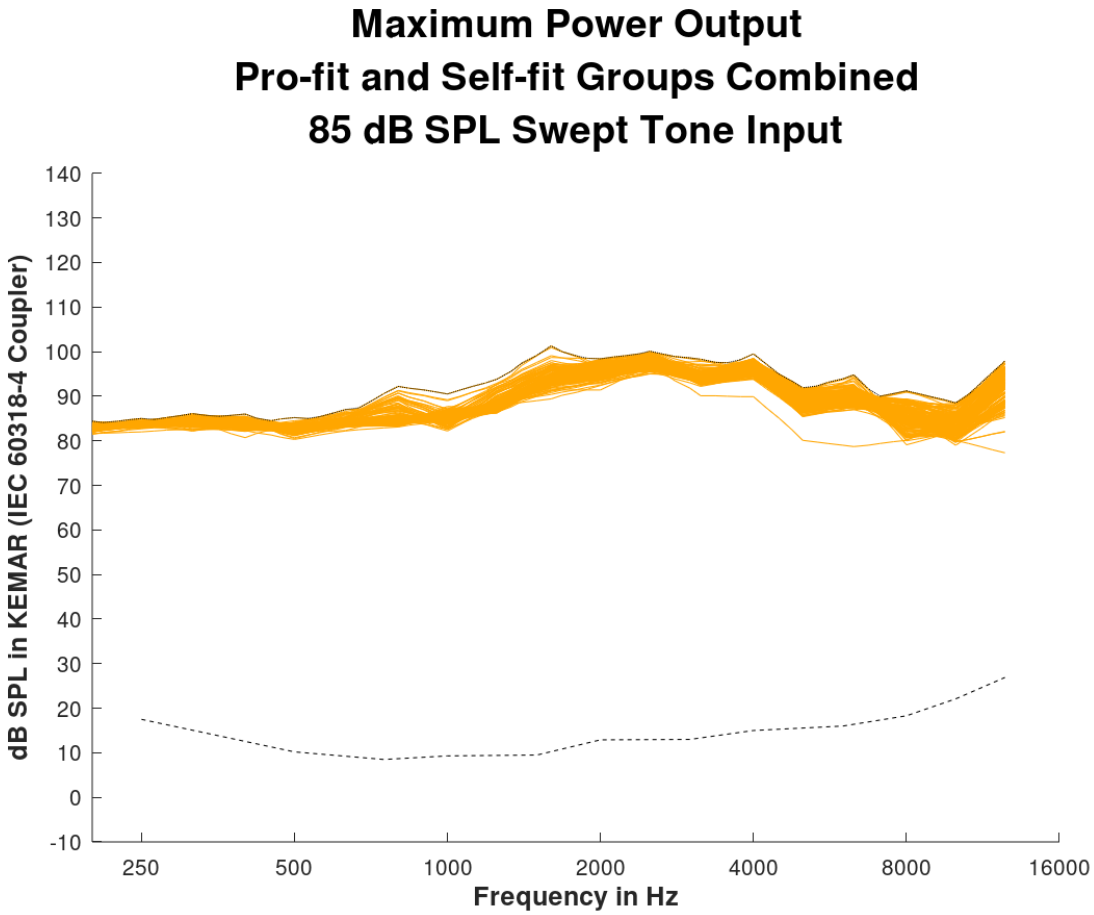


Figure 8. Measured results from the hearing aid minus NAL-NL2 targets for soft level inputs.

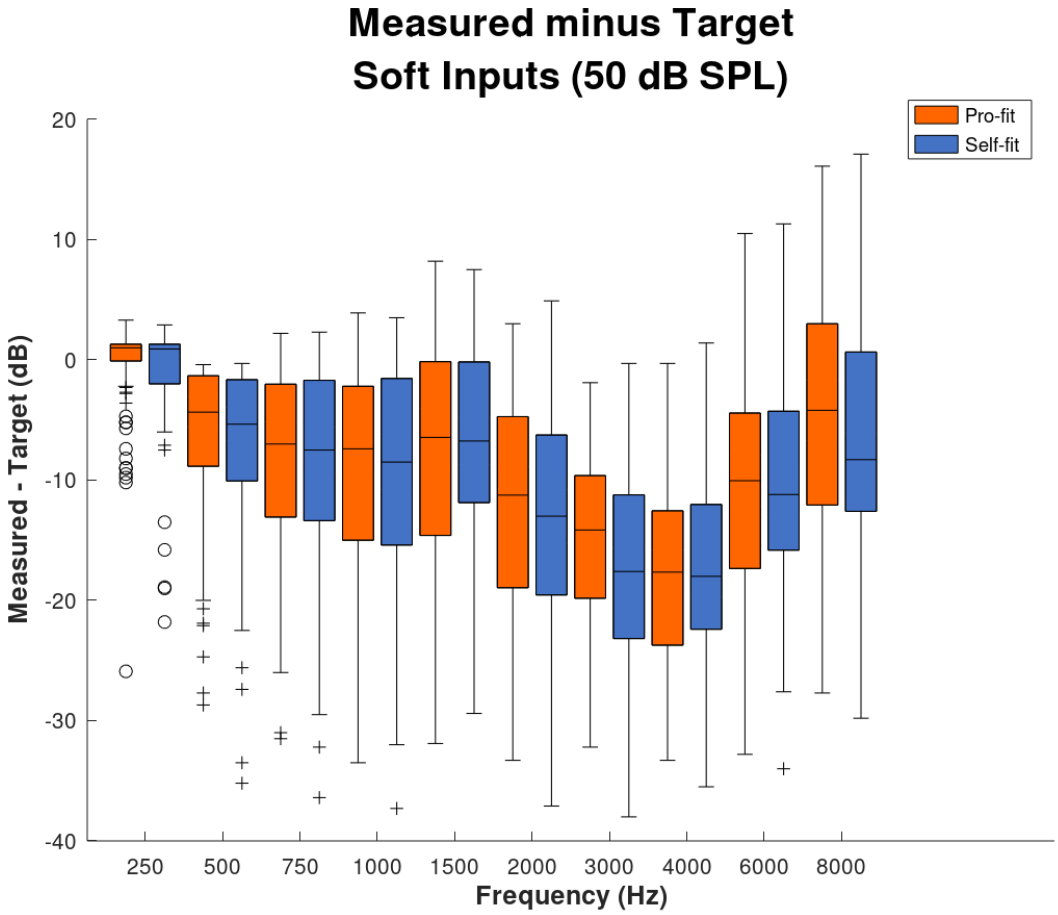


Figure 9. Measured results from the hearing aid minus NAL-NL2 targets for medium level inputs.

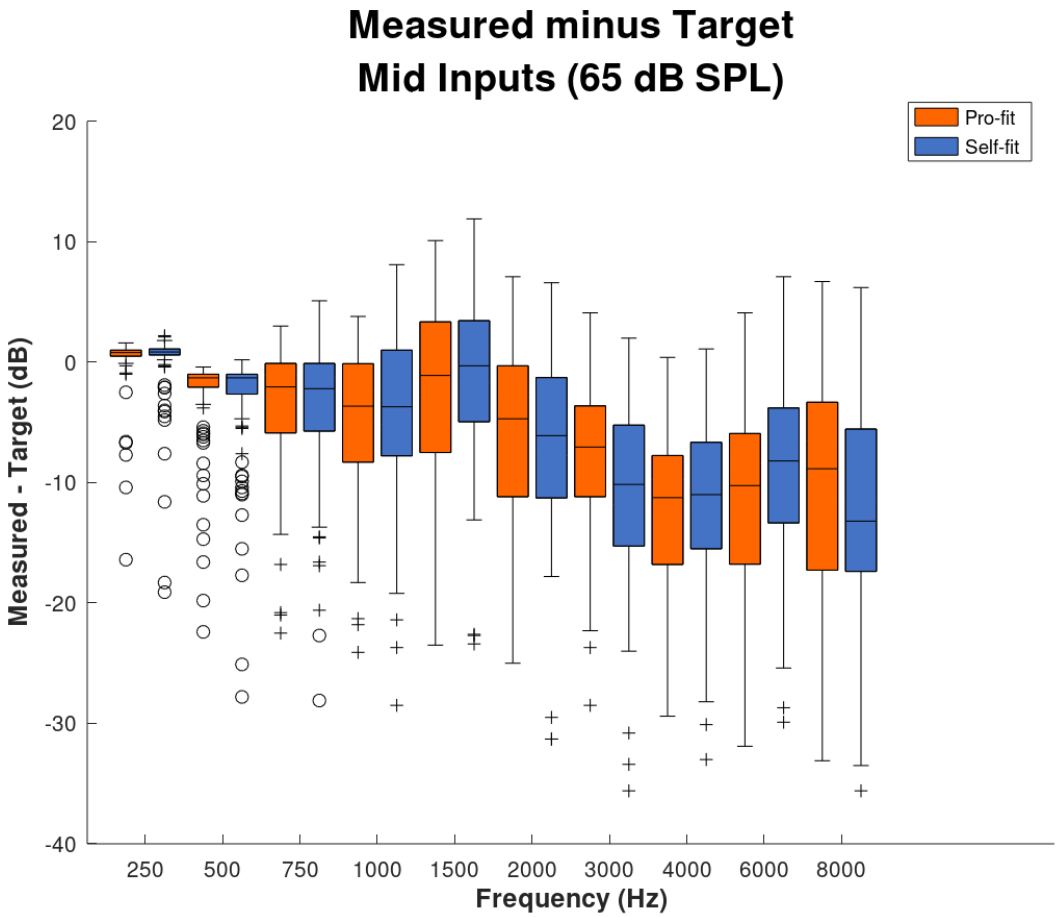


Figure 10. Measured results from the hearing aid minus NAL-NL2 targets for high level inputs.

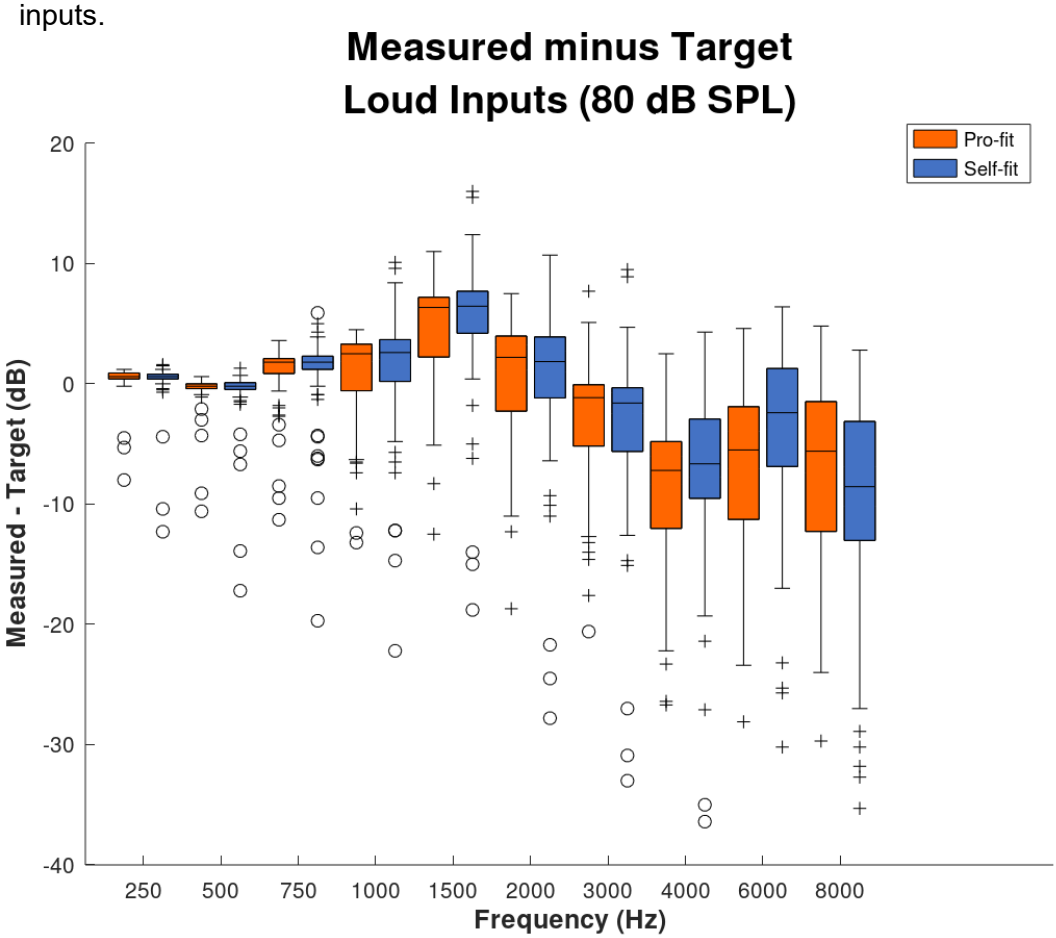
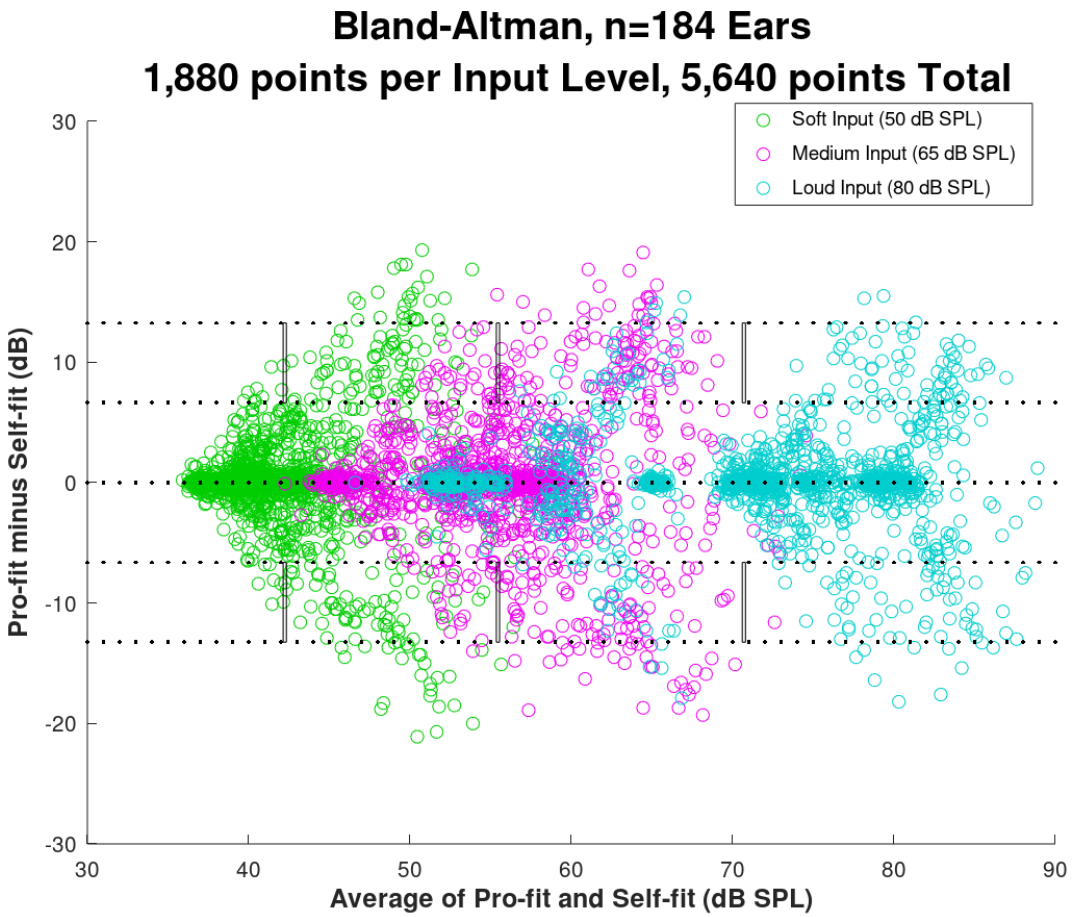


Figure 11 presents the Bland-Altman analysis for all ears. All participants, regardless of group assignment, provided setting data from both the Self-fit procedure and the Pro-fit procedure. The vertical axis of the graph shows differences within participants between their pro-fit and self-fit settings. The horizontal axis is the average dB SPL of the same person's pro-fit and self-fit settings. The vertical lines between one and two standard deviations are the group mean values for soft, medium, and loud inputs, respectively. Values that fall outside the two standard deviation range towards the top of the graph (pro-fit louder than self-fit) mean that the participant was over-fit relative to their NAL-NL2 generated targets, or simply self-selected softer settings than what would have been prescribed by NAL-NL2. Values that fall outside the two standard deviation range towards the bottom of the graph (Self-fit louder than Pro-fit) mean that some participants at some frequencies had a propensity to select louder than what was prescribed to them via NAL-NL2. Both Pro-fit and Self-fit settings were similar in their resulting SPL at the ear canal, documenting similar efficacy of the fitting techniques despite there being minor differences in the technological characteristics.

Figure 11. Bland-Altman analysis of all ears in both Pro-fit and Self-fit groups



The methodology and design of this study was in line with the clinical evaluation of the reference device Bose De Novo (DEN180026) (subjective and objective performance outcomes). These results were also referenced in the 510(k) Summary for the Bose SoundControl BTE hearing aid (K211008) which is a closer physical embodiment to the subject device in that they are both BTE style hearing aids. The results demonstrate that the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application were non-inferior to fitting by an audiologist using best practice fitting algorithms. Effectiveness is also substantially equivalent to the predicate device (Nuheara IQbuds 2 PRO), which was similarly demonstrated to be substantially equivalent to subjective and objective performance outcomes demonstrated in the Bose De Novo (DEN180026) clinical study design referenced by the Bose Soundcontrol (K211008).

This validation of the Sentibo OTC self-fitting methodology for the target population (adults with perceived mild to moderate hearing loss) used an assessment approach similar to that of the reference and predicate devices (Bose Soundcontrol K211008 and Nuheara IQbuds™ 2 PRO K221064 respectively).

12. SUBSTANTIAL EQUIVALENCE

The Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application has the same intended use as the predicate device, the Nuheara IQbuds 2 PRO (K221064). Like the predicate device, the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application is a user-fitted, wireless, air-conduction hearing aid, intended for over-the-counter use by individuals 18 years or older with perceived mild to moderate hearing impairment. Clinical data shows that the effectiveness of the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application is non inferior to fitting by a licensed audiologist with a calibrated clinical audiometer for both self-fitting hearing assessment. Furthermore, human factor testing displayed a high level of user satisfaction and is therefore substantially equivalent to the predicate device in acoustic performance, usability, and safety. Non-clinical performance testing has been conducted to ensure that the device does not raise any questions of safety and effectiveness as established by the predicate device. Device and application firmware and software have been validated per the same standards as used to validate the device and application firmware and software of the predicate device. Lastly, design verification results demonstrate that the subject device has substantially equivalent performance to the predicate device. Lumen 155-SF Hearing Aids are substantially equivalent in intended use and fundamental scientific technology to the Nuheara IQbuds™ 2 PRO Hearing Aids (K221064) and reference devices Bose SoundControl Hearing Aids (K211008) and Bose De Novo (DEN180026). The Bose De Novo (DEN180026) reference device is leveraged for its clinical study design as it demonstrates the safety and efficacy of the self-fitting strategy, while the Bose Soundcontrol (K211008) is leveraged for its use of the same fitting strategy used in the Bose De Novo while being a closer match to the physical embodiment of the subject device in that they are both BTE hearing aids. The Lumen 155-SF Hearing Aids are considered as safe and effective as the predicate device for its intended use when used in accordance with its Instructions for Use.

13. CONCLUSION

The special controls for self-fitting hearing aids as per 21 CFR 874.3325, are met in the following aspects; the clinical data has evaluated the effectiveness of the self-fitting strategy, the electroacoustic parameters (including max output limits, distortion levels, self-generated noise levels, latency, and frequency response) were specified and tested, performance data demonstrates the EMC, electrical and thermal safety of the device. The software verification, validation, and hazard analysis has been performed. The wireless technology performance testing has validated safety of exposure to non-ionizing radiation and validation of wireless technology functions. The usability testing has demonstrated that users can correctly use the device as intended under anticipated conditions of use. In conclusion, the evidence provided demonstrates that the outcomes of the Sentibo self-fit model (with Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application) are comparable to an audiologist's best-practice model. Based on the comparison and analysis above, the Lumen 155-SF Self-Fitting OTC Hearing Aid(s) with Sentibo Application is determined to be substantially equivalent to the predicate device (Nuheara IQbuds 2 PRO K221064).