September 8, 2023

Tuned Ltd
% Shoshana (Shosh) Friedman
Senior Regulatory Affairs Consultant (ProMedoss, Inc.)
ProMedoss Inc
3521 Hatwynn Road
Charlotte, North Carolina 28269

Re: K223848
Trade/Device Name: Intrisound™ Tuned Lumen® 155 Hearing Aids
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: August 10, 2023
Received: August 11, 2023

Dear Shoshana (Shosh) Friedman:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

Shuchen Peng -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K223848

Device Name

Intrisound™ Tuned Lumen® 155 Hearing Aids

Indications for Use *(Describe)*

Intrisound™ Tuned Lumen® 155 are self-fitting, wireless air conduction hearing aids, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. 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
Intrisound™ Tuned Lumen® 155 Hearing Aids
510(k) Number K223848

1. SUBMITTER

Applicant's Name and Address:
Tuned Ltd.
18 Harimon St,
Gan Yoshiya
Israel, 3885000

Primary Contact:
Shoshana (Shosh) Friedman
Senior Regulatory Affairs Consultant
Phone: (704) 430-8695
Email: s.friedman@promedoss.com

510(k) Summary Prepared on: September 5, 2023

2. SUBJECT DEVICE

Trade Name: Intrisound™ Tuned Lumen® 155 Hearing Aids

Classification: **Name:** Self-Fitting Air-Conduction Hearing Aid, Over The Counter
Product Code: QUH
Regulation No: 21 CFR 874.3325
Class: 2
Review Panel: Ear Nose & Throat

3. PREDICATE DEVICE

BHA100 Series Braun® Clear™ Hearing Aid cleared under K212609

4. REFERENCE DEVICE

None

5. DEVICE DESCRIPTION

The Intrisound™ Tuned Lumen® 155 Hearing Aid is a wireless, self-fitting air conduction hearing aid. It features digital signal processing (16 channel wide dynamic input compression, 3 layer fast-acting output compression, 16 channel noise reduction, feedback cancellation), bi-directional microphone with windscreen, volume and program control, 12 band equalizer, self-selectable tube and ear tips, and customization through the Tuned Mobile Application. The Tuned Mobile Application aims to detect accurate auditory thresholds, partnering with a smart phone application to deliver user-customized sound through the Intrisound™ Tuned Lumen® 155 Hearing Aid. These thresholds are used to program the device using a proprietary algorithm.

6. INTENDED USE/INDICATIONS FOR USE

The Intrisound™ Tuned Lumen® 155 are self-fitting, wireless air conduction hearing aids, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care professional.

7. LABELING

Self-selection labeling has been included in the Intrisound™ Tuned Lumen® 155 Hearing Aid User Manual (UM) to mitigate the risk of improper self-selection. The information includes the following:

- Identifying situations in which the Intrisound™ Tuned Lumen® 155 Hearing Aid may help users hear better.
- Identifying situations in which the Intrisound™ Tuned Lumen® 155 Hearing Aid may not be right for users.
- Identifying criteria that indicate users should see a hearing professional.
- Informing users that the Intrisound™ Tuned Lumen® 155 Hearing Aid will not restore normal hearing.
- Informing users that it is good health practice to have hearing loss evaluated by a licensed healthcare professional.

Additionally, the Intrisound™ Tuned Lumen® 155 Hearing Aid User Manual (UM) contains information about the Remote Support Service and the Call Center Telephone Support Service that is available to the users to address concerns and optimize product functionality.

8. SPECIAL CONTROLS

The Intrisound™ Tuned Lumen® 155 Hearing Aid conforms to the special controls stated in 21 CFR 874.3325. These requirements were satisfied through the following:

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

9. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Intrisound™ Tuned Lumen® 155 Hearing Aid has the same intended use and fundamental technology as the predicate device , the BHA100 Series Braun® Clear™ Hearing Aid. In the same manner as its predicate device, the Intrisound™ Tuned Lumen® 155 Hearing Aid 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 subject device is essentially equivalent to the predicate device in product design, dimension, use of Bluetooth technology and utilizing biocompatible materials of high standard.

Table 1 below provides a summarized comparison between the subject device and the predicate device.

Table 1: Comparison Table

Characteristic	PREDICATE DEVICE BHA100 Series Braun® Clear™ Hearing Aid	SUBJECT DEVICE Intrisound™ Tuned Lumen® 155 Hearing Aid	Comparison Analysis
510(k) Number	K212609	K223848	NA
Product Code	QDD	QUH	The OTC version of the self-fitting hearing aid has a different product code (QUH) than when the predicate device was originally cleared as a self-fitting hearing aid. The only differences relevant to this change are updated labeling, design, and performance characteristics required by 800.30 for OTC hearing aids by the enactment of the OTC Hearing Aid Final Rule that became effective on October 17, 2022
Regulation	21 CFR 874.3325	21 CFR 874.3325	Same
Classification Name	Self-Fitting Air-Conduction Hearing Aid, Prescription	Self-Fitting Air-Conduction Hearing Aid, Over The Counter	-
Intended Use	The BHA100 Series Braun® Clear™ Hearing Aid is a self-fitting, air conduction hearing aid, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is adjusted by the user to meet the user's hearing needs. The device is intended for direct-to-consumer sale and use without the assistance of a hearing health care professional.	The Intrisound™ Tuned Lumen® 155 are self-fitting, wireless air conduction hearing aids, intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing healthcare professional.	The intended use of the subject device is similar to the intended use of the predicate device with the appropriate adjustment in accordance with the OTC Hearing Aid Final Rule.
Device Description	The BHA100 Series Braun® Clear™ Hearing Aid is a self-fitting, air conduction hearing aid. It features digital signal processing (16 channel-wide dynamic input compression, 3 channel fast-acting output compression, 16 channel noise reduction, feedback cancellation), bi-	The Intrisound™ Tuned Lumen™ 155 Hearing Aid is a wireless, self-fitting air conduction hearing aid. It features digital signal processing (16 channel wide dynamic input compression, 3 layer fast-acting output compression, 16 channel noise reduction, feedback	The two devices are similar, with additional equalizer adjustments in the subject device, which do not introduce any new safety or effectiveness concerns. Performance testing supports the substantial equivalence.

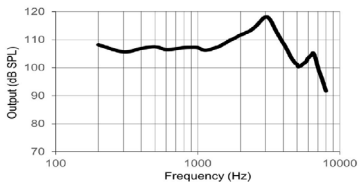
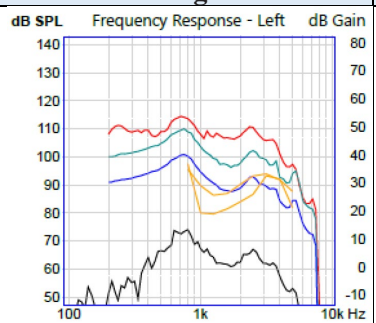
Characteristic	PREDICATE DEVICE BHA100 Series Braun® Clear™ Hearing Aid	SUBJECT DEVICE Intrisound™ Tuned Lumen® 155 Hearing Aid	Comparison Analysis
	directional microphone with windscreen, volume and program control (environment selection – Quiet, Noisy, Concert, TV), 3 channel equalizer, self-adjustable wire and ear tips, and customization through the Braun® Clear™ Mobile Application. The Braun® ClearCheck™ Hearing Test aims to detect accurate auditory thresholds, partnering with a smart phone application to deliver user-customized sound through the Braun® Clear™ Hearing Aid. These thresholds are used to program the device using a proprietary fitting algorithm.	cancellation), bi-directional microphone with windscreen, volume and program control, 12 band equalizer, self-selectable tube and ear-tip (dome), and customization through the Tuned Mobile Application. The Tuned Mobile Application aims to detect accurate auditory thresholds, partnering with a smart phone application to deliver user-customized sound through the Intrisound™ Tuned Lumen® 155 Hearing Aid. These thresholds are used to program the device using a proprietary algorithm.	
Technology	Wireless, self-fitting air conduction hearing aid	Wireless, self-fitting air conduction hearing aid	Same
Housing	BTE (Receiver-in-Canal)	BTE (Receiver-in-Aid)	Similar Both devices are BTE with a difference being that the subject device uses the Receiver-in-Aid assembly instead of a Receiver-in-Canal assembly. Performance testing supports the substantial equivalence.
Power On-Off	Through battery door: Closed = power ON Open = power OFF	Through battery door: Closed = power ON Open = power OFF	Same
Ear-Tips	Two models: Open dome (sizes S, M, L), Closed dome (sizes S, M, L)	Three models: Tulip dome (one size); Double dome (sizes S, M, L), Open dome (sizes S, M, L)	Similar. The subject device offers an additional ear-tip model. Performance testing supports the substantial equivalence
Mobile App	Mobile application on a smartphone with either iOS or Android platforms.	Mobile application on a smartphone with either iOS or Android platforms.	Same
Wireless Communication	Bluetooth protocol	Bluetooth protocol	Same
Wireless User Control Functions via Mobile App	Volume control, program change selection, settings self-selection	Volume control, program change selection, settings self-selection	Same

Characteristic	PREDICATE DEVICE BHA100 Series Braun® Clear™ Hearing Aid	SUBJECT DEVICE Intrisound™ Tuned Lumen® 155 Hearing Aid	Comparison Analysis
Bluetooth Pairing and Control	Pairing and control verification with the paired mobile device.	Pairing and control verification with paired mobile device.	Same
Power Source	Replaceable, disposable, 1.45 Volt, size 312, zinc air battery	Replaceable, disposable, 1.45 Volt, size 312, zinc air battery	Same
Microphones	Bi-directional microphones with windscreen	Bi-directional microphones with windscreen	Same
Device Control	On device and through mobile app	On device and through mobile app	Same
Compression	16 channel, input controlled, output limiting	16 channel, input controlled, output limiting	Same
Noise Reduction	16 channel	16 channel	Same
Feedback Cancellation	Adaptive	Adaptive	Same
Telephone Calls	None	None	Same
Self-Fitting Method	NAL-NL2 based	NAL-NL2 based propriety algorithm	Similar. Performance testing supports the substantial equivalence.
Remote Firmware Update	None	None	Same
Latency	Complies with ANSI CTA 2051-2017 which requires latency ≤ 15 ms	Complies with (e)(3) of 21 CFR 800.30 and with ANSI CTA 2051-2017 which requires latency ≤ 15 ms	Similar. Performance testing supports the substantial equivalence.

ANSI ASA S3.22 Specification of Hearing Aid Characteristics

In order to demonstrate substantial equivalence with the predicate device, the Intrisound™ Tuned Lumen® 155 Hearing Aid was evaluated per ANSI ASA S3.22 for acoustic performance. These results are summarized in Table 2 below.

Table 2: ANSI ASA S3.22 Performance Data

Characteristic	PREDICATE DEVICE BHA100 Series Braun® Clear™ Hearing Aid	SUBJECT DEVICE Intrisound™ Tuned Lumen® 155 Hearing Aid	Comparison Analysis
OSPL90 Curve			Comparable. Performance testing supports the substantial equivalence.

Characteristic	PREDICATE DEVICE BHA100 Series Braun® Clear™ Hearing Aid	SUBJECT DEVICE Intrisound™ Tuned Lumen® 155 Hearing Aid	Comparison Analysis
Max OSPL90	120 dB SPL	114.4 dB SPL	The maximum output of the subject device is lower than the predicate device to comply with the requirements of 21CFR800.30 for OTC hearing aids. Performance testing supports the substantial equivalence.
High Frequency Average OSPL90 (HFA OSPL90)	111 ± 2 dB SPL	109.6 ± 2 dB SPL	Both devices meet the requirements of the standard.
High Frequency Average Full-on Gain (HFA FOG)	40 ± 2 dB	40 ± 2 dB	Both devices meet the requirements of the standard.
Reference Test Gain (RTG)	34 ± 4 dB	34 ± 4 dB	Both devices meet the requirements of the standard.
Frequency Response	200 Hz to 8000 Hz	200 Hz to 8000 Hz	Both devices meet the requirements of the standard.
Frequency Range	<200-8000 Hz	<200 Hz to 7100 Hz	Difference in range is due to the acoustic bandwidth limitations of the Receiver-in-Aid. This difference does not introduce new safety or effectiveness concerns and performance testing supports the substantial equivalence.
Harmonic Distortion	From Engineering Product Specifications: 500 Hz ≤ 1.5% 800 Hz ≤2.0% 1600 Hz ≤ 3.0%	500 Hz ≤ 5.0% 800 Hz ≤ 5.0% 1600 Hz ≤ 5.0%	The subject device complies with ANSI CTA 2051-2017 and 21CFR800.30 that requires total harmonic distortion to be less than 5%.
Equivalent Input Noise (EIN)	<29 dB SPL	<27 dB SPL	Both devices meet the requirements of the standard.
Battery Current	2.5 mA	1.2 mA	Both devices meet the requirements of the standard.

ANSI ASA S3.6 Specifications for Audiometers

Like the Braun® ClearCheck™ Hearing Test feature of the predicate device, the BHA100 Series Braun® Clear™ Hearing Aid, also the Tuned App of the Intrisound™ Tuned Lumen® 155 Hearing Aid was designed to conform to the applicable clauses of ANSI ASA S3.6, as listed in Table 3.

Table 3: ANSI ASA S3.6 Applicable Clauses

Clause #	Clause Title
5.4.3	Unwanted sounds from an earphone
6.1.1	Frequencies and hearing levels
6.1.4	Frequency accuracy

Clause #	Clause Title
6.1.5	Harmonic distortion
7.2	Accuracy of sound pressure for pure tone
7.3.1	Hearing level control increments
7.3.3	Hearing level control linearity
7.5.2	On/off ratio

10. CLINICAL PERFORMANCE TESTING

The clinical performance of the Intrisound™ Tuned Lumen® 155 Hearing Aid was evaluated in several studies. Presented below are the two recent studies.

STUDY 1: ***TU1-RPT-433, Tuned self-test and Tuned self-fitting outputs in comparison with professional hearing test and fitting outputs of hearing-impaired participants***

Study Design

This study of the Intrisound™ Tuned Lumen® 155 Hearing Aid was a prospective, crossover, comparative study designed to validate results of the Tuned self-test compared to a traditional audiometry performed by a professional. In particular, this study aimed to validate a mean absolute difference (MAD) of less than 10 dB for each tested frequency (500, 1000, 2000 and 4000 Hz) between the Tuned self-test and the traditional audiometry and a total MAD[1] of less than 10 dB. This study also aimed to demonstrate that:

- Tuned self-fitting is non inferior to the professional fitting by showing that the MAD from NAL-NL2 per frequency of the Tuned self-fitting is within the range of 5 dB of the MAD from NAL-NL2 of the professional fitting.
- The total MAD of the Tuned self-fitting is within the range of 5 dB from the NAL-NL2 targets.
- The total MAD of the real ear aided responses (REAR) of the Tuned self-fitting and the professional fitting is in the range of 5 dB.
- The maximum power output (MPO) measurements do not exceed 117 dB SPL in any volume control level.

The acceptance criteria presented above were set in accordance to the acceptance criteria applied in the clinical study of the predicate device, the BHA100 Series Braun® Clear™ Hearing Aid, to support the substantial equivalence determination.

The crossover was applied by assigning half of the participants (odd participant numbers) to start with the standard clinical audiometry by a professional, then performed a hearing self-test while the other half (even participant numbers) started with performing the hearing test by themselves, then tested by a professional using standard clinical audiometry.

Study Populations

The study was conducted among a population of 30 adults recruited from private hearing clinics. Table 4 below provides information on the study population.

Table 4: Study 1 Population Summary

Characteristic	N / Total (%)
Age	
18 to 40 years of age	3 / 30 (10.0%)
41 to 60 years of age	4 / 30 (13.3%)

[1] "Total MAD" is the average MAD of all averaged over all tested frequencies.

Characteristic	N / Total (%)
61 to 70 years of age	7 / 30 (23.3%)
71 to 80 years of age	15 / 30 (50.0%)
81 years of age and up	1 / 30 (3.3%)
Sex	
Female	15 / 30 (50.0%)
Male	15 / 30 (50.0%)
Symmetric/Asymmetric Hearing Loss	
Symmetric	21 / 30 (70.0%)
Asymmetric	9 / 30 (30.0%)
Previous Experience with Hearing Aids	
Experienced User	18 / 30 (60.0%)
New User	12 / 30 (40.00%)

Study Results

The results of the primary endpoint, namely, the measured audiometric threshold for each tested frequency of Tuned self-test versus those measured by a licensed audiologist well correlated as shown in Figure 1(a). The mean and ±1 standard deviation of the hearing thresholds, per frequency, obtained by the Tuned self-test and by traditional clinical audiometry performed by a professional are shown in Figure 1(b). The total MAD of the Tuned self-test and the traditional audiometry performed by a professional averaged for all tested frequencies, shown in Figure 1(b), was 5.25 dB with a 95% confidence interval of 4.73 to 5.78 dB, which is well within the accepted criterion of less than 10 dB.

Figure 1(a): Measured Audiometric Thresholds per Frequency

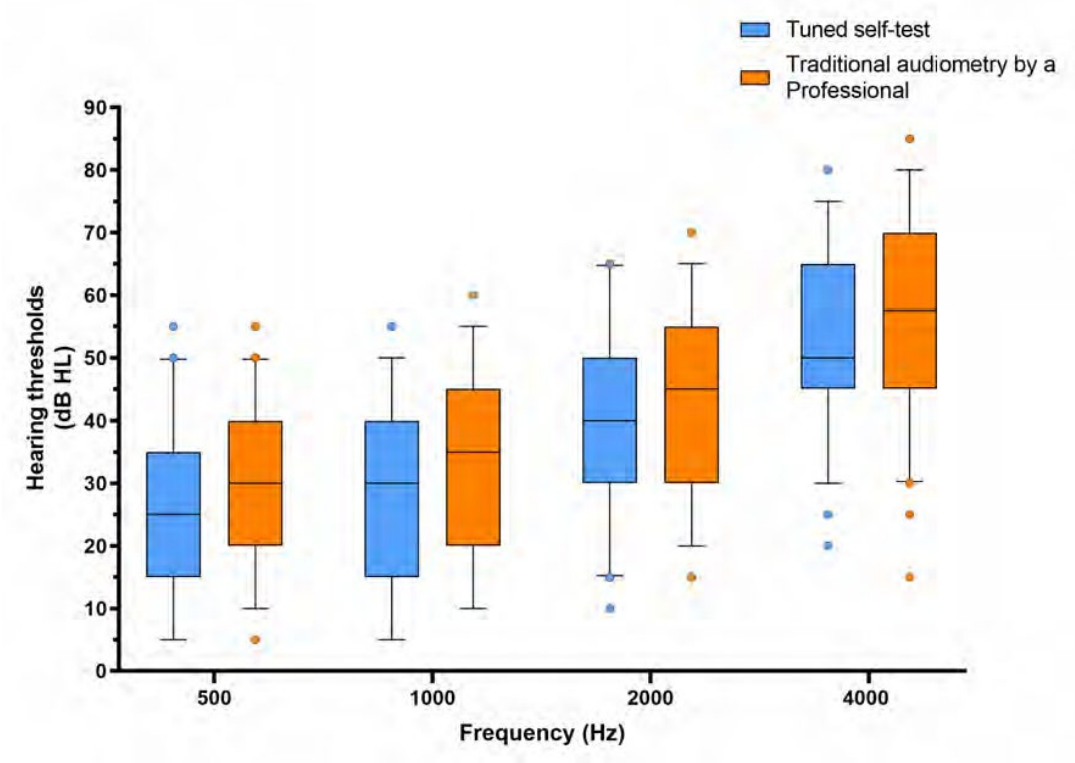
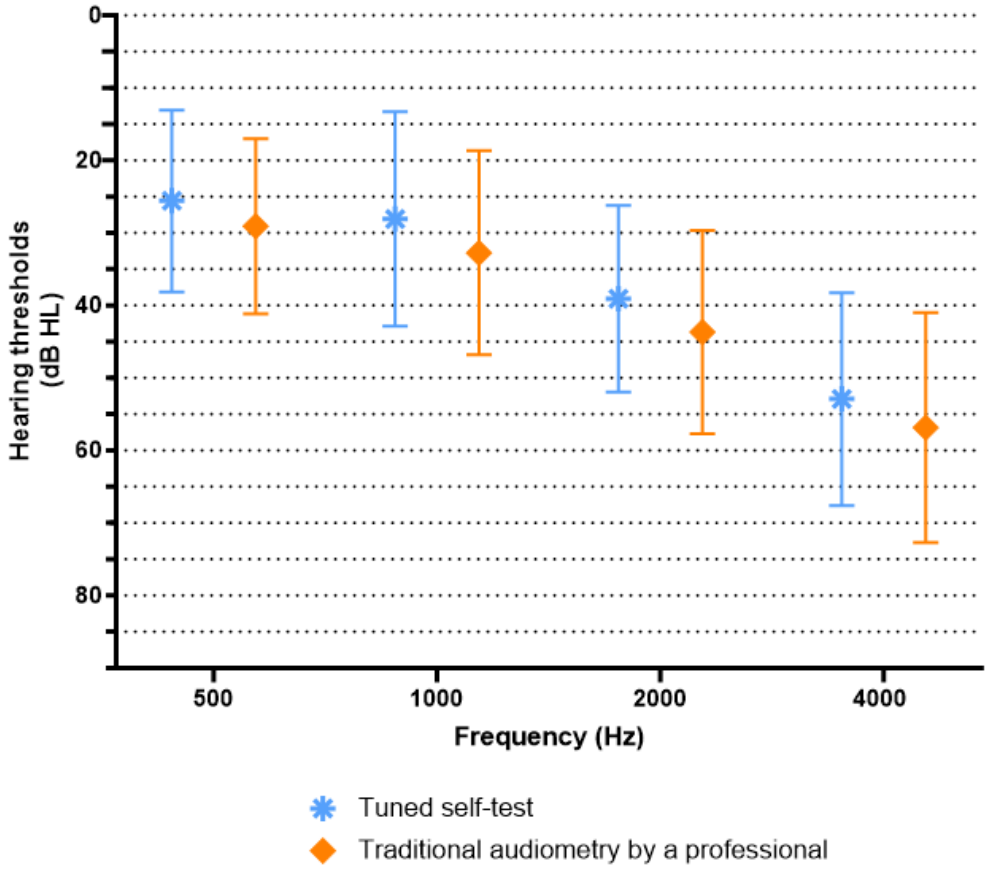


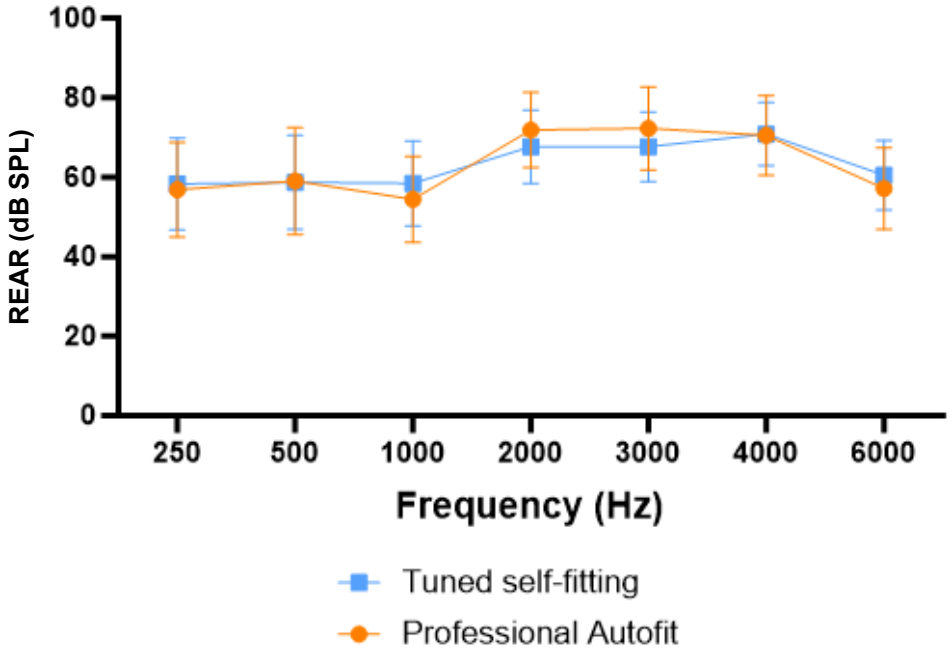
Figure 1(b): Mean and ± 1 standard deviation of the hearing thresholds obtained by the Tuned self-test (Blue) and traditional clinical audiometry performed by a professional (Orange), per frequency



The results of the secondary endpoints showed that:

- The MAD from NAL-NL2 per frequency of the Tuned self-fitting is well within the range of 5 dB of the MAD from NAL-NL2 of the professional fitting.
- The Tuned self-fitting MAD from NAL-NL2 for each frequency is less than 5 dB and the total MAD from NAL-NL2 is 3.37 dB with a 95% Confidence Interval of 3.2 to 3.53 dB, well withing the acceptance criterion of 5 dB.
- The total MAD between the REAR of professional-fitting and Tuned self-fitting is 3.72 dB with a 95% Confidence Interval of 3.55 to -3.89 dB, well within the 5 dB acceptance criterion (see Figure 1(c)).
- All MPO measurements in the real ear were less than 117 dB SPL, well within the acceptance criterion of <117 dB SPL in all volume control levels.

Figure 1(c): Mean ± 1 standard deviation of the REAR following the Tuned self-fitting (Blue) and the professional Autofit (Orange), per frequency



In conclusion, this study supports the clinical performance of the Tuned solution, namely, the Tuned application with the Intrisound Lumen 155 hearing aids, and demonstrates that the Tuned solution is substantially equivalent to the predicate device, the BHA100 Series Braun® Clear™ Hearing Aid, without raising any new safety or effectiveness concerns.

STUDY 2: ***A prospective, crossover randomized controlled trial to compare subjective outcome of a self-fitting process using Tuned App to a licensed professional fitting (NCT05869266)***

Study Design

This study was a prospective, two-arm, two-site, crossover randomized controlled and comparative study, comparing outcomes of two fitting approaches, self-fitting with Tuned mobile app and licensed professional fitting with the same hearing aid device.

Note: Due to the inherent clinician involvement in the tuning process, this study was not investigator-blinded, nevertheless, the meticulous structure of the study aimed to ensure that the lack of blinding did not impact the effectiveness outcomes of the study.

Study Objectives

The primary objective of the study was to compare the subjective outcomes of a self-fitting of the hearing aids done by the participant using the Tuned application and subjective fitting outcomes performed by a licensed professional using the standardized and validated Client Oriented Scale of Improvement (COSI) questionnaire tool.

The secondary objectives were to:

1. Compare the subjective outcomes of a self-fitting of the hearing aids done by the participant using the Tuned application and subjective fitting outcomes performed by a

licensed professional using the standardized and validated International Outcome Inventory- Hearing Aids (IOI-HA) questionnaire tool.

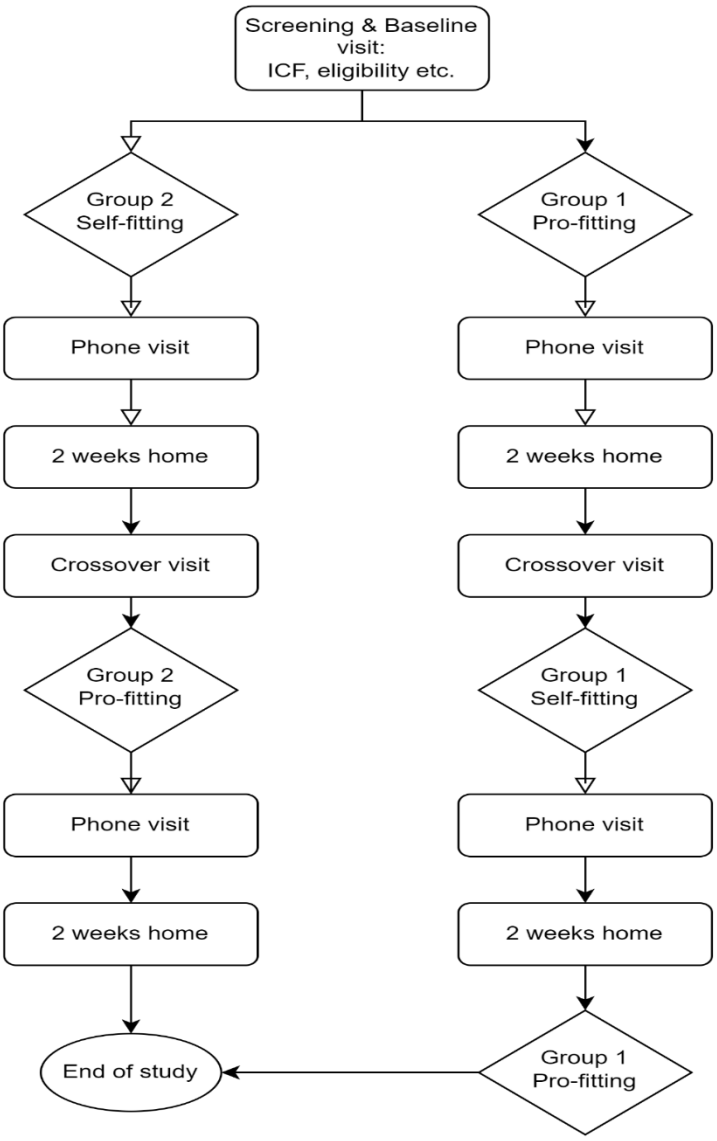
2. Estimate the rate of device and self-fitting related adverse events.

Study Design & Procedures

In this prospective, two-arm, crossover randomized controlled and comparative study, two fitting approaches using the same hearing aid device were compared – self-fitting with Tuned mobile app and fitting by a licensed professional.

The overall flow of the study is presented in Figure 2 below.

Figure 2: Overall Study Flow



Participants in this study underwent the following procedures:

Visit 1: Screening and Eligibility

Upon completion of the informed consent process, subjects underwent a screening process, which included a clinical hearing test conducted by a licensed professional. Subsequently, participants

received hearing aids (HA) along with user manuals. Random assignment placed them into one of two groups:

Group 1: Participants received HA fitting performed by a licensed professional using professional programming tools and the thresholds obtained from traditional audiometry.

Group 2: Participants were provided with Instructions for Use (IFU) and were directed to download the TUNED self-fitting App. They performed self-fitting of the HAs, including a self-hearing test.

Visit 2 and 4: Phone visit

Three (3) days after each fitting, participants were contacted to ensure that the device was functioning properly. If needed, participants were invited to visit the site for technical issue resolution.

Visit 3: Crossover Visit

During this visit, all participants were asked to complete the COSI and the IOI-HA questionnaires. The crossover occurred between Group 1 and Group 2. Participants in Group 1 switched to self-fitting and performed the same actions as Group 2 during their initial visit. Participants IN Group 2 switched to professional fitting and performed the same actions as Group 1 during their initial visit.

Visit 5: End of study

During this final visit, all participants completed the COSI and IOI-HA questionnaires. Participants in Group 1 had their HAs re-fitted by a licensed professional. Finally, all participants received the HAs they had been using throughout the study.

Study Population

The study was completed by a total of forty-one (N=41) participants. Among them, twenty (N=20) participants initially underwent the professional fitting (Group 1) and later transitioned to Tuned self-fitting and twenty-one (N=21) participants began with Tuned self-fitting (Group 2) and subsequently switched to professional fitting. The demographics and baseline characteristics of the study participants, encompassing gender, age and prior experience with hearing aids, is summarized in Table 5.

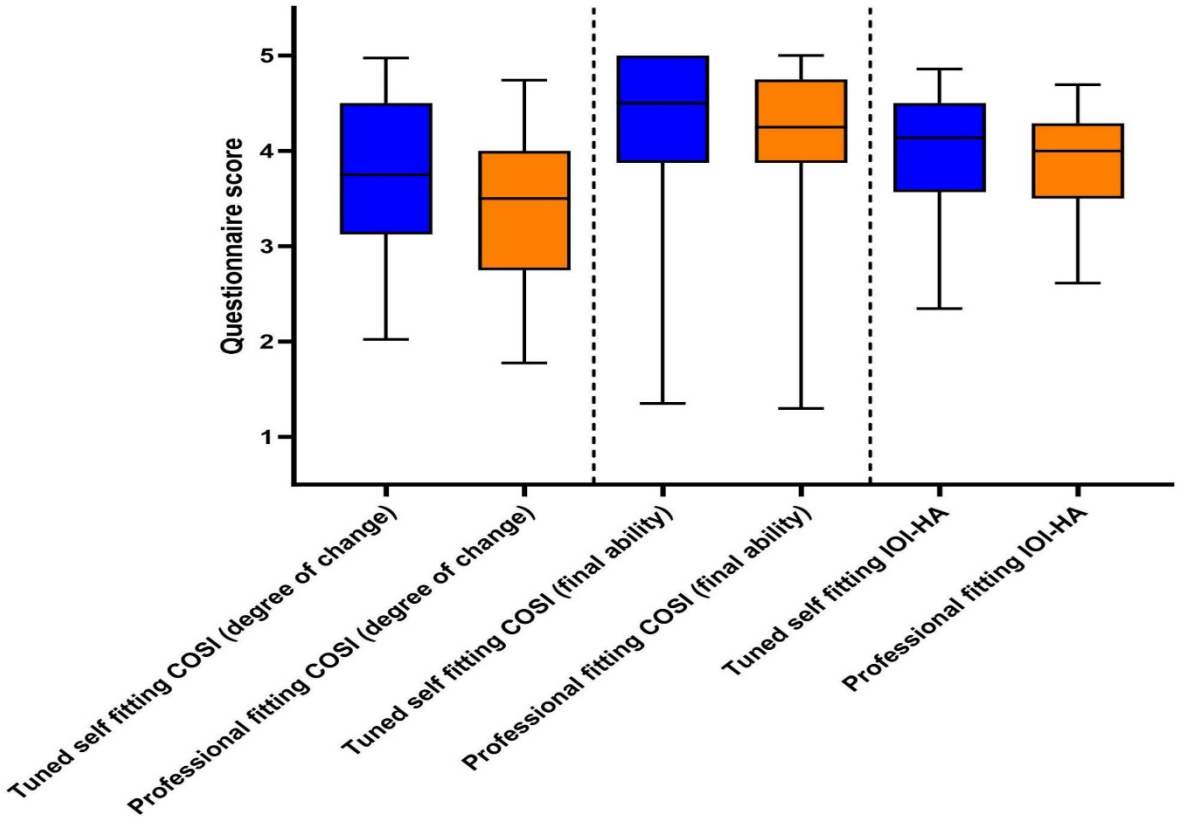
Table 5: Study 2 Subjects Demographics and Baseline Characteristics (N=41)

Variable		N	%	Mean	SD	Range
Gender	**Male**	19	46.3			
	Female	22	53.7			
Age				72.32	9.48	40-91
Previous experience with hearing aids	**Yes**	10	25.0			
	No	31	75.0			

Study Results

Analysis of within-subject improvement between the two fitting methods revealed that Tuned self-fitting demonstrated a higher degree of change in COSI scores (Median = 3.75) compared to professional fitting (Median = 3.50), with z=2.92 and p=.003. Similarly, for IOI-HA scores, Tuned self-fitting exhibited a higher level of improvement (Median = 4.14) compared to professional fitting (Median = 4.00), with a z=2.92 and p=.003. However, no significant difference was observed in COSI 'final ability' between Tuned self-fitting and "professional fitting, median= 4.00), with z=1.19 and p=.233. The results of this analysis are visually presented in Figure 3.

Figure 3: Comparison between Professional fitting and Tuned self-fitting in self-reported questionnaires



The within-subject change analysis based on the initial fitting method revealed that Group 1 participants showed significant improvement in COSI 'degree of change' (Visit 3: Median = 3.12, Visit 5: Median = 4.12, z=3.60, p<.001) and IOI-HA (Visit 3: Median = 3.92, Visit 5: Median = 4.35, z=3.38, p<.001). Marginal significance was found in COSI 'final ability' (Visit 3: Median = 4.37, Visit 5: Median = 4.50, z=1.48, p=.07).

For Group 2, no significant changes were observed in COSI 'degree of change' (Visit 3: Median = 3.75, Visit 5: Median = 3.75, z=-0.16, p=.87), COSI 'final ability' (Visit 3: Median = 4.50, Visit 5: Median = 4.25, z=-0.26, p=.79), and IOI-HA (Visit 3: Median = 4.00, Visit 5: Median = 4.00, z=-0.47, p=.64).

Given the above results, there is a potential sequence effect at Visit 5 based on the initial fitting method; however, there was no apparent sequence effect for Visit 3. A sequence effect may interact with the perceived benefit in the subsequent test condition, introducing a limitation in the interpreting the results. However, the subjective self-fitting outcomes were non-inferior to the professional fit condition in both groups (i.e., not poorer), which is clinically acceptable and the overall goal of this study. Finally, given this potential sequence effect occurs only at Visit 5, and not Visit 3, it is possible the above outcomes are not solely driven by a sequence effect.

No adverse events were observed or reported during the course of the study, therefore, no safety analysis was performed.

Study Conclusion

The clinical data from this study provides evidence of effectiveness of the self-fitting strategy and satisfies the special controls for the self-fitting hearing aids regulation. Participants experienced non-inferior perceptual outcomes and satisfaction with Tuned self-fitting compared to professional fitting.

11. NON-CLINICAL PERFORMANCE TESTING

Non-clinical performance testing was conducted with the Intrisound Tuned Lumen 155 Hearing Aid to provide reasonable assurance of safety and effectiveness as compared to the predicate device, the BHA100 Series Braun® Clear™ Hearing Aid and to support the substantial equivalence determination to the predicate device. A summary of the results are provided in Table 6 below.

Table 6: Summary of Non-Clinical Performance Testing

Performance Topic	Applied Standard/Guidance	Results
Biocompatibility	FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process" (September 2020)	Comply
	ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Pass
	ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
	ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Pass
Basic Safety and Essential Performance	EN 60601-1:2006/A1:2013, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
	IEC 60601-1-11:2015, Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Pass
	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	Pass
Electromagnetic Compatibility	IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests	Pass
	IEC 60118-13:2019, Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices	Pass
Acoustic and Audiometric	ANSI ASA S3.22:2014(R2020), Specification of Hearing Aid Characteristics (see Table 2)	Pass

Performance Topic	Applied Standard/Guidance	Results
	ANSI CTA 2051:2017, Personal Sound Amplification Performance Criteria	Pass
	ANSI ASA S3.6:2018 – Specification for Audiometers	Pass
Wireless and Communication	ANSI C63.19:2019, American National Standard -- Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids	Pass
	ANSI IEEE C63.27-2017, American National Standard for Evaluation of Wireless Coexistence	Pass
	Federal Communications Commission (FCC) Regulation Part 15, Low Power, Non-Licensed Transmitter	Pass
	AAMI TIR69:2017/(R)2020, Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems	Comply
Packaging	ISTA Procedure 3A, Packaged-Products for Parcel Delivery System Shipment 70 Kg (150 Lb) or Less	Pass
Software and Cybersecurity	IEC 62304:2006/Amd 1:2015, Medical device software – Software lifecycle processes	Comply
	FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 2005)	Comply
	FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (October 2014)	Comply

Usability Testing

A usability/human factors validation study of the Intrisound™ Tuned Lumen™ 155 Hearing Aid under the authorization and supervision of WCG IRB was conducted in accordance with:

- FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices" (February 2016); and
- IEC 62366-1:2015+A1:2020 Medical devices – Part 1: Application of usability engineering to medical devices.

The study population included 18 untrained subjects with perceived mild to moderate hearing impairment, representing the intended use population.

Each subject was provided with the Intrisound™ Tuned Lumen®155 Hearing Aids, the User Manual, and the Quick-Guide. The study included a series of activities starting with the subject unboxing the hearing aids, followed by downloading and installing the Tuned App, launching and signing-in, pairing the hearing aid and the app, properly fitting the hearing aids on both ears, performing a self-hearing evaluation, and lastly, controlling the volume and changing the programs of the hearing aids through the Tuned App. The subjects were required to perform these activities without any assistance from a hearing care professional and were observed and assessed by the study team comprised of facilitator, audiologist, and developer.

The results of the study confirmed the adequacy of the fitting process of the Intrisound™ Tuned Lumen®155 Hearing Aids and demonstrated that the device can be used safely, effectively and with a high degree of user performance and satisfaction by representative intended users, according to the intended use, and in the intended use environment.

12. SUBSTANTIAL EQUIVALENCE

The Intrisound™ Tuned Lumen® 155 Hearing Aid has the same intended use and as the predicate device, the BHA100 Series Braun™ Clear® Hearing Aid. Like the predicate device, the Intrisound™ Tuned Lumen® 155 Hearing Aid 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 and human factors/usability data showed that the effectiveness of the Intrisound™ Tuned Lumen® 155 Hearing Aid was non-inferior to fitting by a licensed audiologist with calibrated clinical audiometer for both self-fitting hearing assessment and user satisfaction and is therefore substantially equivalent to the predicate device in acoustic performance, user satisfaction, and safety.

Non-clinical performance testing has been conducted to ensure that the device does not raise any new questions of safety and effectiveness as established by the predicate device. Furthermore, 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. Results of these verification and validation testing demonstrate that the subject device has substantially equivalent performance to the predicate device.

13. CONCLUSION

The Intrisound™ Tuned Lumen® 155 Hearing Aid has substantially equivalent indications and contraindications, technological characteristics, and performance characteristics as these of the BHA100 Series Braun™ Clear® Hearing Aid predicate device. Any minor differences that exist between the devices are within acceptable margins and/or have been addressed through non-clinical and clinical performance testing. We therefore conclude that Intrisound™ Tuned Lumen® 155 Hearing Aid is as safe and as effective as its predicate device, the BHA100 Series Braun™ Clear® Hearing Aid, without raising any new safety and/or effectiveness concerns and meets the special controls provided in FDA regulation 21 CFR §874.3325.