October 30, 2022

Nuheara Limited
% Deborah Arthur
Regulatory Consultant
DArthurConsulting
4830 Randolph Rd., Unit 3302
Charlotte, North Carolina 28211

Re: K221064
Trade/Device Name: Nuheara IQbuds 2 PRO Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QUH
Dated: March 31, 2022
Received: April 11, 2022

Dear Deborah Arthur:

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,

Srinivas Nandkumar, Ph.D.
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)*
K221064

Device Name
Nuheara IQbuds 2 PRO Hearing Aid

Indications for Use *(Describe)*
The IQbuds 2 PRO 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 over the counter sale and 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 – Nuheara Limited

1. SUBMITTER

Nuheara Limited
13555 S.E. 36th St.
Ste. 100
Bellevue, WA 98006 U.S.A.

Contact Person: John Luna

Date Prepared:
October 25, 2022

2. DEVICE [PER 807.92(a)(2)]

Name of Device: Nuheara IQbuds™ 2 PRO Hearing Aid – K221064
Classification Name: Self-fitting Air Conduction Hearing Aid
Common Name: Self-fitting Hearing Aid
Regulation: 21 CFR §874.3325
Regulatory Class: II
Product Code: QUH

3. PREDICATE DEVICE [PER 807.92(a)(3)]

Predicate: Bose Hearing Aid – DEN180026
Reference: BHA100 Series Braun® Clear™ Hearing Aid - K212609

4. DEVICE DESCRIPTION [PER 807.92(a)(4)]

The Nuheara IQbuds 2 PRO Hearing Aid (Model NU320) is a self-fitting wireless air conduction hearing aid (§ 874.3325) consisting of the hearing aids with Ear Tips, Charge Case, Nuheara software, the Nuheara app, and accessories supplied in the carton. The device is indicated for over-the-counter sale.

The hearing aids are designed to be worn in both ears simultaneously with the appropriate size Ear Tips fitted to the sound port of the aid. The device has Ear ID, an innovative hearing assessment system that uses the NAL-NL2 unique programming formula designed for and used globally by hearing aid manufacturers. This hearing profile/personalization system in the IQbuds 2 PRO Hearing Aid assesses the individual's hearing levels across a frequency spectrum to customize the device's amplification specific to their hearing needs. In addition to hearing aid functionality for environmental and directive listening (using the microphones on the aids); the hearing aids can be used for making and receiving phone calls and for streaming audio from a Bluetooth®-compliant mobile device that has been paired with the Nuheara Hearing Aids.

The hearing aids are powered using 3.7V Li-Ion coin cell batteries and the Charge Case powered using a Li-Ion Polymer battery. They can be recharged 'on the go' using the Charge Case, which can fully recharge the hearing aid battery three times before the Charge Case requires recharging. The Charge Case also serves as a helpful carrying case to enable mobile charging and protect the hearing aids while not in use.

5. INTENDED USE

The Nuheara IQbuds 2 PRO self-fitting wireless air conduction hearing aids are intended to amplify sound for individuals with perceived mild to moderate hearing impairment.

6. INDICATIONS FOR USE

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 device is intended for over-the-counter sale and use without the assistance of a hearing care professional.

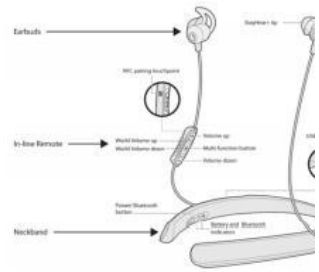
7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The intended use and technological characteristics, e.g., features, parameter settings etc. are substantially equivalent to the predicate device (Bose) cited above. Table 1 summarizes the characteristics of the Nuheara IQbuds 2 PRO Hearing Aids in comparison to the predicate, the Bose Hearing Aid (DEN180026) and, as applicable, the reference device (BHA100 Series Braun® Clear™ Hearing Aid - K212609). The BHA100 device serves a reference device as the self-fitting strategy (i.e., self-administered hearing test and subsequently applied prescription) is similar to the subject device.

Table 1. Summary of Technological Characteristics

	Subject	Predicate	Reference	Discussion of Differences
Device Trade name	**Nuheara IQbuds™ 2 PRO**	**Bose Hearing Aid**	**BHA100 Series Braun® Clear™ Hearing Aid**	
510k Number	K221064	DEN180026	K212609	
Product code	QUH	QDD	QDD	The over-the-counter version of the self-fitting hearing aid has an updated product code to differentiate it from the DTC version (QDD). The only difference is the updated labeling as required by the enactment of the OTC Hearing Aid Final Rule on October 17, 2022.
Regulation number	21 CFR 874.3325	21 CFR 874.3325	21 CFR 874.3325	Same as predicates
Regulation name	Self-fitting air conduction hearing aid	Self-fitting air conduction hearing aid	Self-fitting air conduction hearing aid	Same as predicates
Intended Use	The IQbuds 2 PRO Hearing Aids is intended to amplify sound for individuals with perceived mild to moderate hearing impairment.	The Bose Hearing Aid is intended to amplify sound for individuals with perceived mild to moderate hearing impairment.	The BHA100 Series Braun® Clear™ Hearing Aid is intended to amplify sound for individuals with perceived mild to moderate hearing impairment.	Same as predicates

Indications for Use	The IQbuds 2 PRO 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 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.	The BHAI00 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.	Same as predicate and reference
Technology	Rechargeable batteries Lithium-ion polymer	Rechargeable battery Lithium- ion polymer		Subject device battery is recharged in a 'Charge Case' that stores and charges the battery at the same time. While the predicate recharges by use of an AC plug adapter and connector into hearing aid neckband to recharge. Neither hearing aid can be used while charging. The difference in recharging process does not introduce new issues of safety as both devices meet same battery standards

	Subject	Predicate		
Device Trade name	**Nuheara IQbuds™ 2 PRO**	**Bose Hearing Aid**	**BHA100 Series Braun® Clear™ Hearing Aid**	**Discussion of Differences**
Housing	In-the-ear hearing aid 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)	Hearing aid neckband housing that connects to both the left and right ear units with user controls on right earbud wire. 		Although the subject device hearing aid housing is wireless and in- the ear instead of a neckband with wired earbuds, the difference in housing does not raise different questions of safety or effectiveness.
Input signal compression	Wide dynamic range compression	Wide dynamic range compression		Same as predicate
Microphones	Microphones in the earbud, can be configured by the user during use; via the Nuheara app. To configure the microphones to switch between omni-directional and directional sound, in the Nuheara app you can toggle the FOCUS feature ON / OFF.	Microphones in earbud may, during use, be configured by the user in omni-directional or directional modes		The subject device, as well as the predicate, allow for omni-directional and speech focus options.

Battery Life	Per CTA 2051 (4.1-4.17) Battery life of up to 8 hrs	Per CTA 2051 (4.1-4.7) Battery life of 10 hrs		Subject device has a 'portable' Charge Case for charging the hearing aids at any time or place should there be a need for extended use. The battery life is similar to that of the predicate. However, the subject device offers the advantage of 'on the go' charging. The battery life or the 'on the go' charging does not raise any new issues of safety and effectiveness.
Noise Reduction	Hybrid Active Noise Cancellation	Active Noise Reduction (ANR)		The subject device performs in a similar manner to predicate and does not raise different issues of

	Subject	Predicate	Reference	Discussion of Differences
Device Trade name	**Nuheara IQbuds™ 2 PRO**	**Bose Hearing Aid**	**BHA100 Series Braun® Clear™ Hearing Aid**	
				effectiveness
Self-fitting method	Subject device uses a proprietary Ear ID, a validated NAL-NL2 fitting algorithm,	Loudness and Fine-tuning app-based Controllers. Utilizes a proprietary fitting algorithm.	Braun ClearCheck Hearing Test is a feature of the BHA100 Braun Clear hearing aid. This feature validated using performance standard testing, detects auditory thresholds and partnered with a smartphone app, delivers user-customized auditory signal/sound through the hearing aid.	The Ear ID feature in the subject device yields hearing assessment which then calculates and applies NAL-NL2 target gains to self-fitting hearing aid using the app in user smartphone. Human factors assessment validates that the user can effectively utilize the proprietary Ear ID feature to profile their hearing needs and thus 'calibrate' the device to their unique hearing profile. In measures of clinical effectiveness, the subject device performance in quantitative and qualitative measures is consistent with the reference device and does not raise different issues regarding safety and effectiveness
Mobile App	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.		The subject and predicate device utilize a mobile app user interface on a smart device in a similar manner and do not raise different issues regarding effectiveness.

Remote firmware updates	The subject device via the Nuheara app allows for remote firmware updates to the hearing aids.	The predicate does allow for remote firmware updates.		Allowing for remote firmware updates are assessed as part of the cybersecurity risk process and risk mitigations are developed per the device hazard analysis. This does not raise different questions of safety and effectiveness.

	Electro-Acoustic Characteristics per ANSI S3.22 and CTA 2051:2017			
Electro-Acoustic Characteristics	**Subject Device**	**Predicate**	**Reference BHA100 Series Braun Clear**	**Discussion of Differences**
Latency Clause 4.8	5ms	Less than or equal to 15 ms	Non-applicable	The subject device meets the requirements, same as predicate.
Frequency response	200Hz - 8000 Hz	200Hz – 8000 Hz		The subject device has the same frequency response as the predicate.
Input Distortion Clause 4.4.2	Less than or equal to 5% (measure is 0.7%)	Less than or equal to 5%		The subject device meets the requirements, same as predicate.
Equivalent Input Noise (EIN) Clause:6.12	28.5 dB SPL	26 dB		The subject device meets the requirements, same as predicate.
Harmonic Distortion Clause 6.11	0.2%	Less than or equal to 5%		The subject device meets the requirements, same as predicate.
Max OSPL90 Clause 6.2	109.6 dB SPL	115 dB SPL	120 dB SPL	The subject device meets the requirements, same as predicate.
HFA OSPL90 Clause 6.3	100.9 dB SPL	112 dB SPL	111 ± 2 dB SPL	The subject device meets the requirements and is lower than the predicate device, which does not introduce any questions of safety.

HFA FOG Clause 6.5	29.4 dB SPL	43 dB	40±2 dB	The subject device meets the requirements and is lower than the predicate device, which does not introduce any questions of safety.
RTG Clause 6.7	24.4 dB SPL	36 dB	34 +/- 4dB	The subject device meets the requirements and is lower than the predicate device, which does not introduce any questions of safety.

8. NON-CLINICAL PERFORMANCE DATA

Both the subject and predicate devices were 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 Measurements
- CTA 2051: 2017

In order to establish substantial equivalence to the predicate device, Nuheara evaluated the electroacoustic data as found in the predicate and required under Special Controls for 21 CRF §874.3325. As seen in the Electro-Acoustic Characteristics per ANSI S3.22 and CTA 2051:2017 table above, the measurement for the specific cited clauses indicates that the Nuheara IQbuds 2 PRO Hearing Aids are substantially equivalent in acoustic performance to the predicate, Bose Hearing Aid (DEN180026).

Electrical Safety, EMC, Battery Safety, Software and Labeling

- IEC 60601-1; 2005 + AMDI:2012.
- IEC 60601-1-2; 2014, AMDI:2020;Part 1-2:
- IEC 60601-2-66:2019[1]
- IEC 62133-2, Edition 1.0: 2017-02
- ISO 15223-1:2016 Medical devices
- IEC62304: 2006; 1st Edition +A1:2016; Software life cycle processes

Consistent with the predicate device, the Nuheara IQbuds 2 PRO Hearing Aids 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, the Bose Hearing Aid.

9. 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.

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

[1] Not FDA recognized but applicable to the device and its intended use; also included to be consistent with predicate, Bose Hearing Aid.

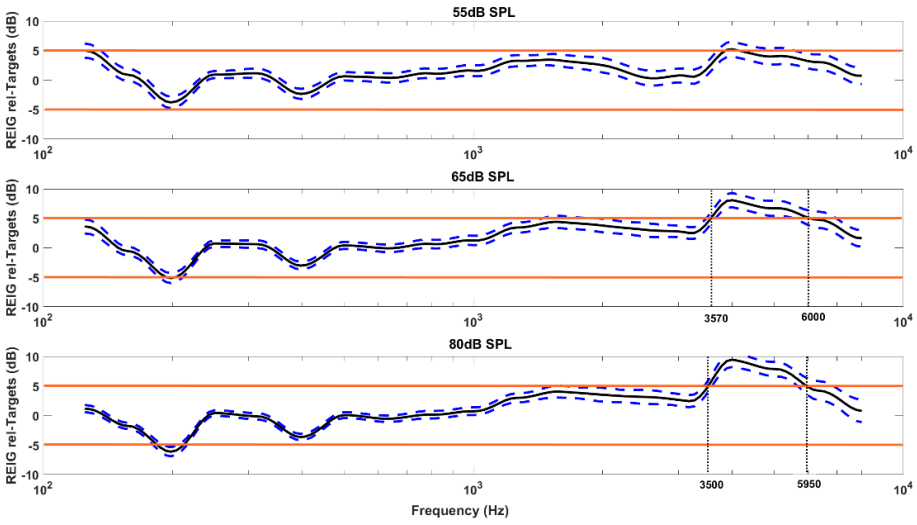
design changes to the user interface to accommodate the user needs. The same cross-functional team reviewed and approved the Summative Evaluation Report. The evaluation provided evidence that the device was safe and effective to operate by the intended user when used in accordance with its intended use.

Overall, the human factors study demonstrated that the usability of the Nuheara hearing aid was analyzed, verified, and validated for its intended use, intended use environment and the implemented mitigations for user training and device labeling are adequate.

Clinical Performance

Clinical Performance with the Nuheara IQbuds 2 PRO Hearing Aid was assessed with a prospective investigation of the clinical effectiveness with the Nuheara IQbuds 2 PRO self-fitting hearing using standard audiological assessment metrics in 43 adults, mean age of 50 and self-identified with a perceived mild to moderate hearing loss. They were evaluated using well established clinical measures and real-world scenarios. This validation of the Nuheara 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 BHA100 Series Braun Clear Hearing Aid by assessing clinical effectiveness *quantitatively* and *qualitatively*. Those measures involved the following:

- Quantitatively comparing target gain from the audiologist determined REM using standard audiologic practice (NAL-NL2) against the participant completed self-fit using the Nuheara Ear ID feature.



This figure shows the REIG calculated deviations measures and corresponding 95% confidence intervals, based on the t-score method. The figure shows that REIG lies with ± 5 dB from NAL-NL2 target for frequencies below 3.5 kHz.

- Assessing perceptual measures of device effectiveness by utilizing the well characterized and validated APHAB and SSQ-12 self-reported questionnaires and EMA for real-time self-reporting of user listening experience while aided

(shown below).

A Real Ear Insertion Gains measure (REIG) allowed for amplification levels calculated and applied by Ear ID™ to be compared to the targeted NAL-NL2 prescription. The results indicate that when averaged across the group, the Ear ID™ provides acceptable margins of amplification, within ± 5 dB range, from prescribed targets.

APHAB

The Ear ID feature of the IQbuds 2 PRO was developed and validated by National Acoustics Laboratories (NAL) to the widely recognized hearing aid fitting algorithm, NAL-NL2. This fitting strategy has been incorporated and validated in multiple clinical studies as the primary 'comparator' representing a best fit *(e.g., Valente et al., 2018)*. In the IQbuds 2 PRO clinical performance assessment, the APHAB was used to compare participant subjective outcomes in the unaided and aided conditions.

Clinical effectiveness of the IQbuds 2 PRO *Self-Fit* hearing aid is evidenced in the analysis of the four subscales of the APHAB questionnaire (Ease of Communication (EC), Reverberation (RV), Background Noise (BN), and Aversiveness (AV) of sound). The results of the 43 subjects in a global score are shown on the table below. The global scores are calculated as the average of the EC, BN, and RV subscale scores.

	UNAIDED					AIDED				
	EC	**BN**	**RV**	**AV**	**Global Score**	**EC**	**BN**	**RV**	**AV**	**Global Score**
Mean	22.4	45.1	31.8	41.9	33.1	14.3	28.3	23.6	41.2	22.1
SD	19.1	19.1	18.7	23.9	16.9	16.3	17.8	17.4	26.8	15.3
N	43	43	43	43	43	43	43	43	43	43

This table shows the mean scores for the 43 subjects from the study of clinical performance in each of the APAB subscales and then the overall Global Score. Benefit is derived by comparing unaided to aided values.

Results indicated the Nuheara *Self-Fit* aided condition improved the mean scores (i.e., lower scores) for ease of communication in noise by 17.8 points; in quiet by 7.4 points; and in reverberation - 8.2 points, out of a total score of 100. The global improvement was 11 points better when aided with the IQbuds 2 PRO *Self-Fit*. The Unaided to Aided difference in the scores were well within the published 5-30 (%) percentile norms for the APHAB *(Cox and Alexander, 1995)*.

As the IQbuds 2 PRO Self-Fit is based on NAL-NL2, it is appropriate to look at other studies of hearing aids programmed to meet that industry standard formula with REM confirmation and incorporating the APHAB as a measure of clinical effectiveness. The most significant to date would be *Valente M. et al., 2018*, which had a similar study

population across multiple criteria and also incorporated a 4-week aided, home trial. Their study showed a significant advantage for the NAL-NL2 fitted subjects (compared to manufacturer *default fit*) with a significant median advantage of 4.2% ($p < 0.04$; 95% confidence interval (CI): 20.6–13.2%) for the programmed-fit (NAL-NL2) compared with the *first-fit* for the background noise subscale problem score for the APHAB. These outcomes incorporating NAL-NL2 fit-programs as a comparator are also consistent with the findings of *Abrams, Chisolm, McManus, & McArdle (2012)* in a similar study.

SSQ

This validated assessment scale groups 'sound' into three main categories – speech, spatial and quality. The intent is to determine the individual's perceived level of disability in different listening environments. When outcomes between the IQbuds 2 PRO participants were compared to those in the Valente study using the NAL-NL2 fit, the results were comparable for all three categories:

SSQ	Valente	Nuheara
Speech	6.8	7
Spatial	7.5	7.1
Qualities	7.9	7.2

Speech in Noise

A modification of the BKB-like sentences (*Bench et al., 1979)* was adapted by NAL to Australian English. The sound field configuration introduced multi-talker babble noise presented from three loudspeaker locations at 120-, 180- and 240-degrees locations. On average, participants scored 56% recall when unaided or aided without directional microphone but with performance increasing to 86% when directionality was employed.

10. STATEMENT OF SUBSTANTIAL EQUIVALENCE

The Nuheara IQbuds 2 PRO™ Hearing Aid has the same intended use and indications for use compared to the predicate device with comparable technological characteristics and principles of operation that do not raise different questions of safety and effectiveness. The Nuheara IQbuds 2 PRO™ Hearing Aid uses a similar self-fitting strategy as the reference device. Also similar to the reference device, the subject device leverages subjective measures to demonstrate clinical benefit.

Non-clinical performance testing demonstrated equivalent safety and effectiveness with respect to electrical safety, EMC, radio/telecommunications, and electroacoustic testing as compared to the predicate, the Bose Hearing Aid (DEN180026). Similarly, software was developed, tested, and documented in accordance with software development and testing pursuant to *IEC 62304:2006+A1:2015,* FDA's "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" (2005) and with "Content of premarket Submissions for Management of Cybersecurity in Medical Devices"

(2018) and demonstrated that the IQbuds 2 PRO Hearing Aid should perform as intended in the specified use conditions consistent with that reported by the predicate, the Bose Hearing Aid.

The usability testing and clinical study provided validation that risks to health have been mitigated to an acceptable level as well as reasonable assurance of safety and effectiveness and evidence of clinically meaningful benefit to a population experiencing obstacles to accessibility and affordability of hearing aids. The IQbuds 2 PRO Hearing Aid is substantially equivalent in intended use to the predicate device, the Bose Hearing Aid (DEN180026) and similar to the self-fitting strategy in the reference device, the BHA100 Series Braun® Clear™ Hearing Aid. The clinical performance data for the IQbuds 2 PRO Hearing Aids shows reasonably similar outcomes to that in literature that used NAL-NL2 in a professional fit condition.

Overall, based on the results of non-clinical, usability and clinical performance testing, risks to health have been mitigated to an acceptable level and the benefits of the IQbuds 2 PRO clearly outweigh the potential risks to health providing evidence that IQbuds 2 PRO is substantially equivalent to the Bose Hearing Aid when used as intended and in accordance with its Instructions for Use.