January 5, 2022

Kaz USA, Inc., a Helen of Troy Company
Matt Baun
Director of Clinical & Regulatory Affairs
400 Donald Lynch Boulevard, Suite 300
Marlborough, Massachusetts 01752

Re: K212609
Trade/Device Name: BHA100 Series Braun Clear Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Name: Self-fitting air-conduction hearing aid
Regulatory Class: Class II
Product Code: QDD
Dated: December 1, 2021
Received: December 6, 2021

Dear Matt Baun:

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,

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)*
K212609

Device Name
BHA100 Series Braun® Clear™ Hearing Aid

Indications for Use *(Describe)*
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.

Restricted Device (per 21 CFR 801.420 and CFR 801.421).

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

I. SUBMITTER

Kaz USA, Inc., a Helen of Troy Company
400 Donald Lynch Blvd., Suite 300
Marlborough, MA 01752
Establishment Registration Number: 3006169981
Contact Person: Matt J. Baun, Director of Clinical & Regulatory Affairs
Phone: (508) 490-7240
E-mail: MBaun@helenoftroy.com
Date Prepared: 10-August-2021

II. SUBJECT DEVICE

Trade / Device Name: BHA100 Series Braun® Clear™ Hearing Aid
Regulation Number: 21 CFR 874.3325
Regulation Medical Specialty / 510k Review Panel: Ear Nose & Throat
Regulation Name: Self-Fitting Air-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: QDD
510(k) number: K212609

III. PREDICATE DEVICE

Bose SoundControl™ Hearing Aids – 510(k) # K211008

IV. REFERENCE DEVICE

iHearTest – 510(k) # K151025

V. 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-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.

VI. INTENDED USE / INDICATIONS FOR 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.

VII. LABELING

Self-Selection Labeling has been included in the BHA100 Series Braun® Clear™ Hearing Aid Owner's Manual (OM) / Instructions for Use (IFU) to mitigate the risk of improper self-selection. Summarized, it addresses the following:

- Identifying situations in which the BHA100 Series Braun® Clear™ Hearing Aid may help users hear better.
- Identifying situations in which the BHA100 Series Braun® Clear™ Hearing Aid may not be right for users.
- Identifying criteria that indicate users should see a hearing professional.
- Informing users that the BHA100 Series Braun® Clear™ 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.

VIII. SPECIAL CONTROLS

The BHA100 Series Braun® Clear™ 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

IX. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject device, the BHA100 Series Braun® Clear™ Hearing Aid, and the predicate device, the Bose SoundControl™ Hearing Aids (510(k) # K211008), are self-fitting, direct-to-consumer, hearing aids indicated for individuals 18 and 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.

Both devices contain the following, similar technological characteristics:

- Self-Fitting Hearing Aid
- Home Healthcare Environment Use
- Bluetooth
- On Device Controls
- App (Braun® Clear™ App)
- Software Platform Compatibility (iOS, Android)
- Replaceable, Disposable, 1.45 Volt, Size 312, Zinc Air, Hearing Aid Battery Power Source
- Traditional, Receiver-In-Canal (RIC) / Behind-The-Ear (BTE) Form Factor
- Bi-directional Microphones
- User-Adjustable Wire
- Different Size Ear Tips

The BHA100 Series Braun® Clear™ Hearing Aid includes:

- 16-Channel Noise Reduction
- Feedback Cancellation
- 16-Channel Wide Dynamic Input Compression
- 3-Channel Fast-Acting Output Compression
- 3-Channel Equalizer (Low / Mid / High)
- Open and Closed Ear Tips in 3 Sizes (Small, Medium, Large)

Any differences in technological characteristics between the subject and predicate device have been addressed through testing to a known performance standard or by showing equivalency in terms of function. Therefore, these differences are not significant and do not change the safety or effectiveness of the subject device.

X. CLINICAL PERFORMANCE TESTING

Study Design

The pivotal clinical study of the BHA100 Series Braun® Clear™ Hearing Aid was a prospective, randomized, two-arm, multicenter (4 clinical sites) clinical validation study. In Phase 1 of the study, the safety and effectiveness of the self-fitting hearing test of the BHA100 Series Braun® Clear™ Hearing Aid was evaluated through quantitative measures (audiometric thresholds and REM) while comparing it to fitting of the same hearing aid by a licensed audiologist using a calibrated, clinical audiometer. In Phase 2 of the study, subjects were randomized 1:1 into the 2 fitting strategies and completed a 60-day field trial in either the "Audiologist-Fit" group (audiologist fit only, with no ability to take the self-fitting hearing test, as would be the case for a typical, professionally-fit hearing aid) or a "Self-Fit" group (no access to audiologist fit, self-fit completed through the Braun® Clear™ Mobile Application and re-fitting with the Braun® ClearCheck™ Hearing Test enabled). During this phase, the safety and effectiveness of the whole BHA100 Series Braun® Clear™ Hearing Aid System (hearing aid and mobile application) was evaluated through qualitative measures (the Client-Oriented Scale of Improvement, a series of questionnaires assessing the benefit associated with the hearing aid to the individual user).

Subject Demographics

The study was conducted among a population of 80 adults. **Table 1** below, provides information on the total study population and **Table 2** provides information on subject demographics by cohort ("Audiologist-Fit" / "Self-Fit") of the study.

Table 1 – Study Population Summary

Characteristic	N / Total (%)
Age	
18 to 40 years of age	5 / 80 (6.25%)
41 to 50 years of age	2 / 80 (2.5%)
51 to 60 years of age	18 / 80 (22.5%)
61 to 70 years of age	36 / 80 (45.0%)
71 to 90 years of age	18 / 80 (22.5%)
81 to 90 years of age	1 / 80 (1.25%)
Sex	
Female	44 / 80 (45.3%)
Male	36 / 80 (54.7%)
Baseline hearing loss duration (as reported by the subject)	
Have no hearing loss	5 / 80 (6.3%)
Have recently emerged hearing impairment (less than 1 year ago)	11 / 80 (13.8%)
Have had hearing loss for 1 year or longer	64 / 80 (80.0%)
Baseline hearing loss severity (tested by audiologist, based on worse ear)	
No hearing loss	3 / 80 (3.75%)
Mild hearing loss	34 / 80 42.5%)
Moderate hearing loss	33 / 80 (41.25%)
Severe hearing loss	10 / 80 (12.5%)
Hearing Loss Type	
Conductive	0 / 80 (0%)
Sensorineural	80 / 80 (100%)
Mixed	0 / 80 (0%)
Hearing aid use (as reported by the subject)	
Experienced User	27 / 80 (33.8%)
New User	53 / 80 (66.3%)

Table 2 – Subject Demographics: By Cohort

Demographic Category	All Subjects	
	Audiologist-Fit	**Self-Fit**
Sample Size	40	40
6 Frequency PTA* (dB HL) (Mean, STD)	38.1, 11.9	38.4, 14.5
Sensorineural Hearing Loss† (# of subjects)	40	40
Conductive Hearing Loss† (# of subjects)	0	0
Mixed Hearing Loss† (# of subjects)	0	0
No Hearing Loss (# of subjects)	2	1
Mild Hearing Loss (# of subjects)	15	19
Moderate Hearing Loss (# of subjects)	18	15
Severe Hearing Loss (# of subjects)	5	5
Asymmetric Hearing Loss‡ (# of subjects)	3	5
New Hearing Aid Users (# of subjects)	26	27
Experienced Hearing Aid Users (# of subjects)	14	13
Age (Years) (Mean, STD)	63.9, 12.4	63.1, 11.6
Sex (Female, Male)	21, 19	24, 16

* Thresholds measured at 250 Hz, 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz, and 6000 Hz (**Figure 2a** and **Figure 2b**)
† Conductive component if Air Bone Gap ≥ 15 dB HL at 500, 1000, 2000, and 4000 Hz
‡ Defined as a difference in PTA that is greater than 15 dB between ears (American Academy of Otolaryngology–Head and Neck Surgery)

Study Procedures

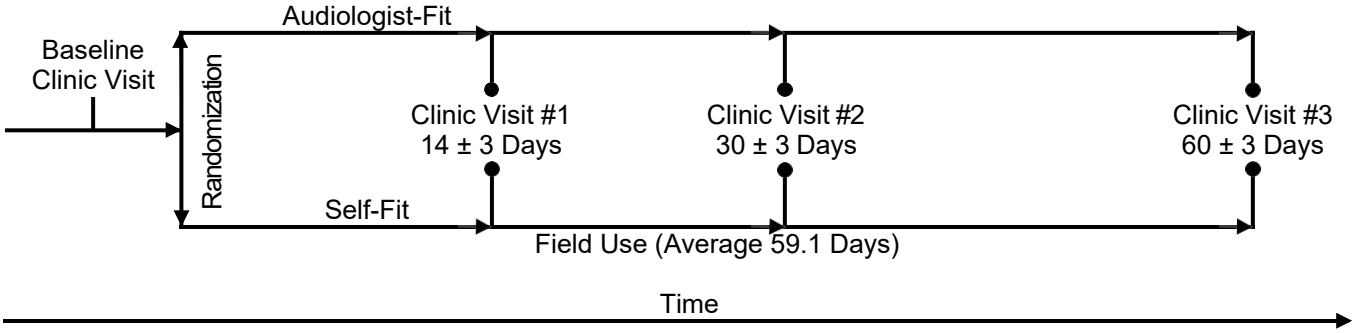
The study was divided into 2 phases. The objective of Phase 1 was to validate the effectiveness of the self-fitting hearing test of the BHA100 Series Braun® Clear™ Hearing Aid, while the objective of Phase 2 was to demonstrate the effectiveness of the whole BHA100 Series Braun® Clear™ Hearing Aid System (the hearing aid and mobile application).

Phase 1 of the study evaluated the BHA100 Series Braun® Clear™ Hearing Aid through quantitative measures during a single, initial, "Baseline" clinic visit. As direct comparison to the Bose SoundControl™ Hearing Aids (510(k) # K211008) was not possible, due to them not being available at the time of the study, the BHA100 Series Braun® Clear™ Hearing Aid was compared to fitting of the same hearing aid by a licensed audiologist using a calibrated, clinical audiometer. All 80 subjects performed both self-fitting of the BHA100 Series Braun® Clear™ Hearing Aid and underwent clinical audiometry to determine their audiometric thresholds, which could then be programmed into the hearing aids, as needed. All 80 subjects underwent Real Ear Measures (REM) while wearing the BHA100 Series Braun® Clear™ Hearing Aid using both their self-fitting thresholds, and the audiologist determined thresholds.

Phase 2 of the study evaluated the BHA100 Series Braun® Clear™ Hearing Aid System through qualitative measures over the course of four (4) clinic visits ("Baseline", "14 ± 3 days", "30 ± 3 days", and "60 ± 3 days"). All 80 subjects completed Client Oriented Scale of Improvement (COSI) baseline (unaided) questionnaires and were then sent home for 60 days of field use with the BHA100 Series Braun® Clear™ Hearing Aid, randomized (1:1) to either the "Audiologist-Fit" or "Self-Fit" fitting strategies. COSI questionnaires were completed at each of the remaining 3 clinic visits to assess the improvement of listening / hearing goal achievement (participant-set goals) at 60 days from baseline values. The COSI was assessed on ability to achieve improvement (based on participant-reported, adjective-scale) and compared between self-fitting and audiologist-led fitting groups.

Figure 1 below, depicts the experiment timeline for the pivotal clinical study of the BHA100 Series Braun® Clear™ Hearing Aid.

Figure 1 – Experiment Timeline



Study Results

Phase 1 Primary Endpoint:

The primary endpoint of Phase 1 was the mean absolute difference (MAD) between the Pure Tone Average (PTA), across all frequencies, of subject hearing loss in dB from the self-fitting hearing test, performed by a subject using the Braun® Clear™ mobile application in an audiometric sound booth, and the PTA of subject hearing loss in dB from the audiologist executed hearing test, each performed in an audiometric sound booth.

The MAD was 2.8 dB, with a 95% Confidence Interval of 2.4 dB to 3.2 dB and $p<0.05$, and within the 10 dB margin of the acceptance criteria (**Figure 2a**). Additionally, the thresholds per frequency between those measured during self-fitting versus those measured by a licensed audiologist using a calibrated clinical audiometer were well correlated (**Figure 2b**).

Figure 2a

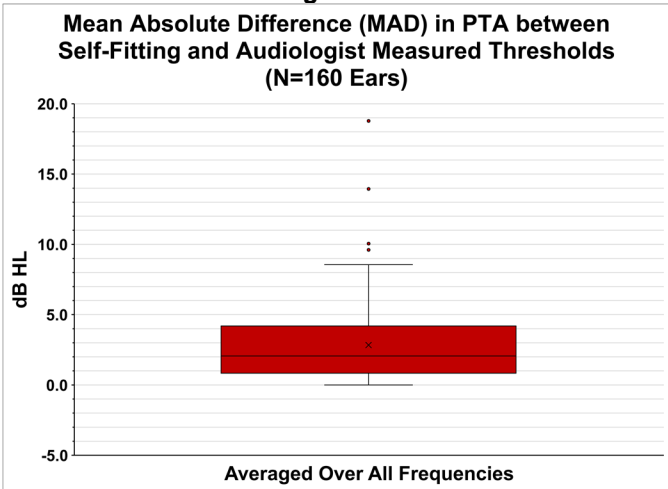
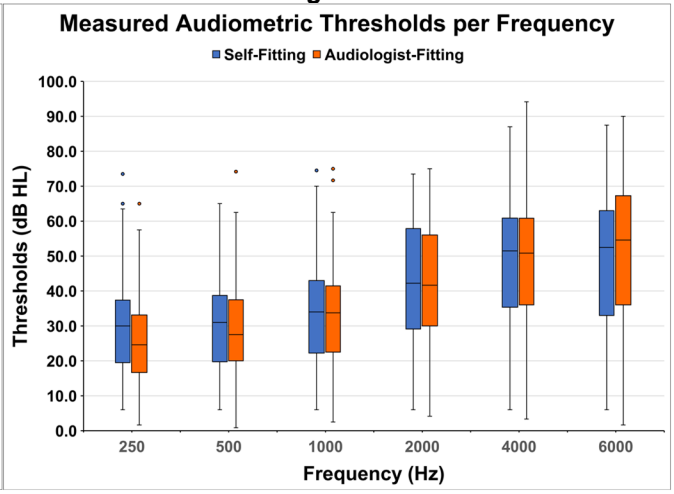


Figure 2b



Phase 1 Secondary Endpoint:

The secondary endpoint of Phase 1 was the MAD between target gain, assessed using Real Ear Measurements (REM), of the BHA100 Series Braun ® Clear™ Hearing Aid, resulting from a self-fitting hearing test, performed by a subject using the Braun® Clear™ mobile application in an audiometric sound booth, and resulting from an audiologist executed hearing test performed in an audiometric sound booth.

The MAD was 0.7 dB, with a 95% Confidence Interval of 0.5 dB to 0.9 dB and $p<0.05$, and within the 5 dB margin of the acceptance criteria (**Figure 3a**). Additionally, the Mean Absolute Difference (MAD) in Real Ear Measures (REM) from NAL-NL2 targets, per frequency, between a self-fitting versus an audiologist fitting were well correlated (**Figure 3b**).

Figure 3a

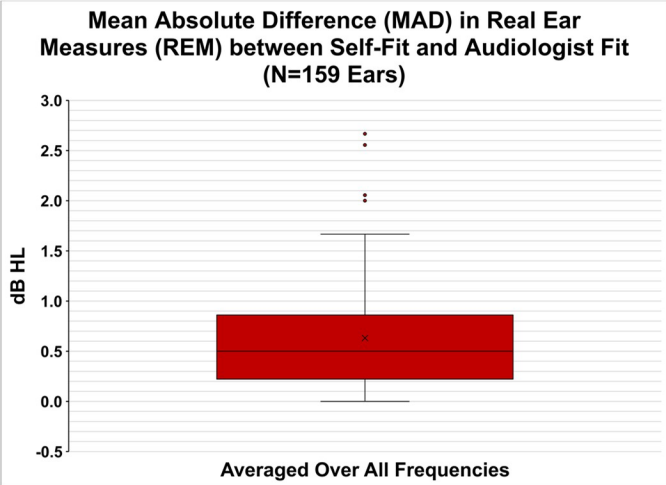
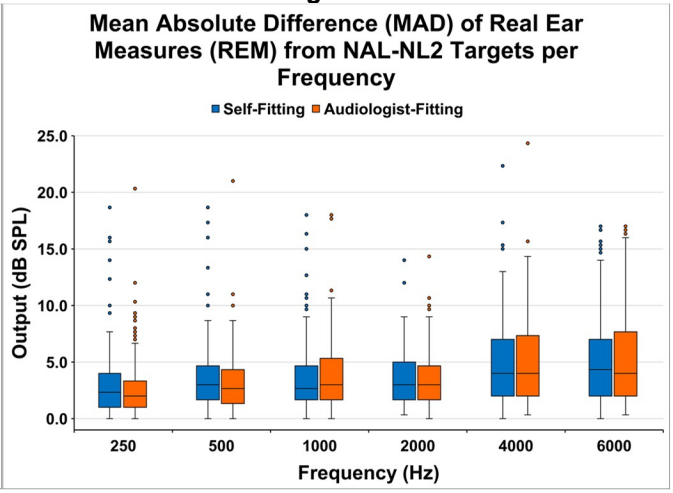


Figure 3b



Phase 2 Primary Endpoint:

The primary endpoint of Phase 2 was the improvement of listening / hearing goal achievement (participant-set goals) at 60 days from baseline values, to subjectively validate the intervention of the BHA100 Series Braun® Clear™ Hearing Aid, using the Client-Oriented Scale of Improvement (COSI). The COSI was assessed on ability to achieve improvement (based on participant-reported, adjective-scale) and compared between self-fitting and audiologist-fitting groups.

The difference in mean COSI scores between self-fitting and audiologist-fitting groups was -0.04, with a 95% Confidence Interval of -0.35 to 0.28 and a p-value for non-inferiority of 0.004, and within the 0.5 margin of the acceptance criteria (**Figure 4a**). Additionally, COSI scores for subjects in both the self-fitting and the audiologist-fitting groups showed a similar spread and distribution (**Figure 4b**).

Figure 4a

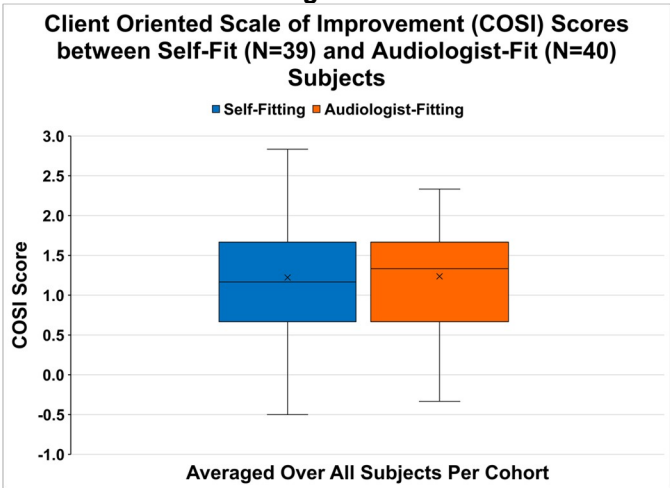
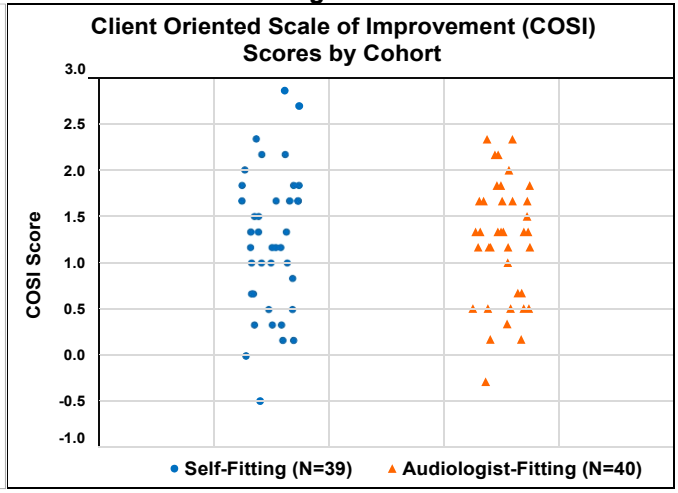


Figure 4b



Effectiveness:

The endpoints for the BHA100 Series Braun® Clear™ Hearing Aid pivotal clinical study focused on determining an equivalence in performance between a fitting by the user of the BHA100 Series Braun® Clear™ Hearing Aid and a fitting by a licensed, independent, study audiologist using a clinical audiometer calibrated according to ANSI standards. Using methods identical to those used to validate the predicate device, the endpoints compared the hearing assessment algorithm of the BHA100 Series Braun® Clear™ Hearing Aid through quantitative measures, and user satisfaction with the BHA100 Series Braun® Clear™ Hearing Aid through qualitative measures. The study results demonstrated that the BHA100 Series Braun® Clear™ Hearing Aid was non-inferior to fitting by a licensed audiologist with a calibrated clinical audiometer for both self-fitting hearing assessment and user satisfaction. Hence, the study met its primary and secondary endpoints with the required statistical significance. Therefore, the effectiveness of the BHA100 Series Braun® Clear™ Hearing Aid as 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, without the assistance of a hearing care professional is substantially equivalent to the effectiveness reported for the predicate device, the Bose SoundControl™ Hearing Aids (510(k) #K211008).

Safety:

There was one (1) report of an Adverse Event (AE) and one (1) report of a Serious Adverse Events *(SAE)* during the pivotal clinical study across four clinical sites. The AE was that a subject reported feeling off-balance following device fitting, which resolved immediately. The SAE, which was a hospitalization due to the subject being found unconscious in their home, was adjudicated by the clinical site PI as not being related to the investigational hearing aids. Tabulating this data equates to one (1), device attributable Adverse Event over the course of a collective 4729 days of subject use of the BHA100 Series Braun® Clear™ Hearing Aid or one (1) in approximately 13 years of total use-time. Considering events known to occur in other air-conduction hearing aids as documented in the Manufacturer and User Facility Device Experience (MAUDE) database, these events occur more frequently in the broader intended population than were observed in the study population. Therefore, the BHA100 Series Braun® Clear™ Hearing Aid met the requirements for safety and has a similar safety profile to the predicate Bose SoundControl™ Hearing Aid.

Summary:

Based on the clinical performance as documented in the pivotal clinical study, the BHA100 Series Braun® Clear™ Hearing Aid was found to be substantially equivalent to the predicate device, having a safety and effectiveness profile that is similar.

XI. NON-CLINICAL PERFORMANCE TESTING

Non-clinical performance testing was conducted on the BHA100 Series Braun® Clear™ Hearing Aid to provide reasonable assurance of safety and effectiveness as compared to the predicate device, the Bose SoundControl™ Hearing Aids (510(k) # K211008) and to provide support of substantial equivalence determination to the predicate device. A summary of results can be seen in ***Table 3*** below:

Table 3 – Summary of Non-Clinical Performance Testing

Compliance / Testing Standard(s) / FDA Guidance	Test Purpose	Result
IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	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 systems used in the home healthcare environment	Basic Safety and Essential Performance	Pass
IEC 60601-2-66:2017 Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems	Basic Safety and Essential Performance	Pass
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	Electromagnetic Compatibility	Pass
IEC 60118-13:2019 Electroacoustics – Hearing aids – Part 13: Electromagnetic compatibility	Electromagnetic Compatibility	Pass
ANSI ASA S3.22:2014 – Specification of Hearing Aid Characteristics	Acoustic Performance	Pass
ANSI CTA 2051:2017 – Personal Sound Amplification Performance Criteria	Acoustic Performance	Pass
ANSI ASA S3.6:2018 – Specification for Audiometers	Audiometric Performance	Pass
• IEC 62304:2015 – Medical device software – Software lifecycle processes • FDA Guidance FDA-2020-D-0957 - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - May 11, 2005	Software Verification and Validation	Pass
• ISO 10993-1:2018 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process • ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity • ISO 10993-10:2010 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization • ISO 10993-12:2021 - Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials • ISO 10993-23:2021 - ISO 10993-23:2021, Biological Evaluation of Medical Devices – Part 23: Tests for Irritation • FDA Guidance FDA-2013-D-0350- Use of International Standard ISO 10993-1, “Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process” - September 4, 2020	Biocompatibility	Pass
• IEC 62366-1:2015 – Medical devices – Part 1: Application of usability engineering to medical devices • IEC 60601-1-6:2013 - Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability • FDA Guidance FDA-2011-D-0469 - Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff - February 3, 2016	Summative Usability / Human Factors Validation	Pass
• FDA Guidance FDA-2018-D-3443 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - October 18, 2018 • FDA Guidance FDA-2015-D-5105 - Postmarket Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff - December 28, 2016	Cybersecurity Compliance	Pass
• Federal Communications Commission, Part 15 Low Power Communication Device Transmitter • IEEE / ANSI C63.27:2017 - Evaluation of Wireless Coexistence • AAMI TIR 69:2020 - Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems	Bluetooth SIG Compliance	Pass

Compliance / Testing Standard(s) / FDA Guidance	Test Purpose	Result
ANSI C63.19:2019 - Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids	Radio Frequency Immunity	Pass
ISTA 3A – Packaged Products for Parcel Delivery System Shipment 70 Kg (150 Lb) or Less	Package Testing	Pass

NOTE: Full Non-Clinical Performance Testing results, including acceptance criteria and testing performed to internal specifications, are reported in the 510(k) submission.

ANSI ASA S3.22:2014 MEASUREMENTS:

In order to demonstrate substantial equivalence with the predicate device, the BHA100 Series Braun® Clear™ Hearing Aid was evaluated per ANSI ASA S3.22 for acoustic performance. The results are summarized in ***Table 4*** below:

Table 4 - ANSI ASA S3.22 Performance Data

Test	Predicate Device: Bose SoundControl™ Hearing Aids – K211008	Subject Device: BHA100 Series Braun® Clear™ Hearing Aid	Discussion
OSPL90 curve	*Figure 2* (Left)	*Figure 2* (Right)	Same
Max OSPL90	113 dB SPL	120 dB SPL	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
HFA OSPL90	106 dB SPL	111 ± 2 dB SPL	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
HFA FOG	30 dB	40±2 dB	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
RTG	29 dB	34 +/- 4dB	Adequate for fitting moderate hearing loss (55 dBHL) as prescribed by NAL-NL2
Frequency response	<200 Hz to 8000 Hz	200 Hz to 8000 Hz	Same
Harmonic Distortion	<1%	From Engineering Product Specifications: 500 Hz ≤ 1.5% 800 Hz ≤ 2.0% 1600 Hz ≤ 3.0%	Equivalent, as the values listed in the EPS were to allow for device-to-device variability From Bench Testing: 0.4% @ 500 Hz 0.5% @ 800 Hz 0.6% @ 1600 Hz
EIN	<27 dB SPL	<29 dB SPL	Same
Battery Current	2.8 mA	2.5 mA	Same

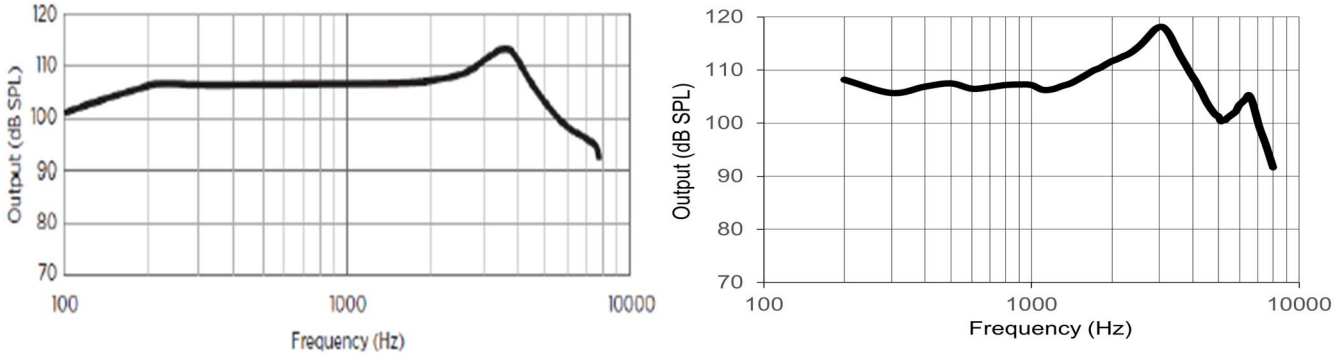


Figure 5: *OSPL90 curves for the Bose SoundControl™ Hearing Aids (left panel) and the BHA100 Series Braun® Clear™ Hearing Aid (right panel), as measured in a 2cc coupler.*

Based on the above information, the BHA100 Series Braun® Clear™ Hearing Aid are substantially equivalent to the predicate device, the Bose SoundControl™ Hearing Aids (K211008).

USABILITY TESTING:

A summative usability / human factors validation test of the BHA100 Series Braun® Clear™ Hearing Aid was conducted in accordance with the following:

- IEC 62366-1:2015 – Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 60601-1-6:2013 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- FDA Guidance - Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff (2016)

The summative usability / human factors validation test included 36 untrained participants representing the intended user population (individuals 18 year of age or older with perceived mild to moderate hearing impairment), each of whom performed hands-on use scenarios and knowledge tasks (Critical Tasks) with the BHA100 Series Braun® Clear™ Hearing Aid, including the Braun® Clear™ App, accessories, and provided user instructional materials. After completion of the series of Critical Tasks, the moderator asked open-ended questions to collect participants' subjective assessments of the relative ease or difficulty of the Critical Tasks to further evaluate safety and usability. These tasks included two critical tasks related to sound awareness safety and the need for hearing protection in loud listening environments, as well as an assessment of the ability to self-fit the hearing aids and select the correct ear tips. Other tasks also included:

- Creating an account on Braun® Clear™ App
- Opening the battery door, correctly installing a battery, and closing the battery door
- Fitting the hearing aid on the ear
- Properly inserting the foam tip into the ear canal
- Changing the environmental setting
- Changing the volume setting via the app
- Changing the volume setting via the hearing aid
- Reducing device feedback

The test found that the BHA100 Series Braun® Clear™ Hearing Aid is safe and effective for the intended users, uses, and use environments.

XII. SUBSTANTIAL EQUIVALENCE

The BHA100 Series Braun® Clear™ Hearing Aid has the same intended use and as the predicate devce, the Bose SoundControl™ Hearing Aids (K211008). Like the predicate device, the BHA100 Series Braun® Clear™ 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 data shows that the BHA100 Series Braun® Clear™ Hearing Aid was non-inferior to fitting by a licensed audiologist with a 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 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.

XIII. REFERENCE DEVICE

The Braun® ClearCheck™ Hearing Test is a feature, which aims to detect accurate auditory thresholds by partnering with a smart phone application to deliver user-customized sound through the Braun® Clear™ Hearing Aid, which is intended for individuals 18 years of age or older with perceived mild to moderate hearing impairment. There are only 3 possible options displayed to the user after taking the Braun® ClearCheck™ Hearing Test: no hearing loss is detected (Normal or No hearing loss), hearing loss is detected (Mild or Moderate hearing loss), and more significant than Mild to Moderate hearing loss is detected (Severe or Profound hearing loss). If a user is detected to have Severe or Profound hearing loss, the app will recommend that the user see a hearing care professional.

This feature is a key technological difference between the BHA100 Series Braun® Clear™ Hearing Aid system and the predicate device. In order to address this technological difference, the iHearTest (K151025) was used as a reference device to support the audiometric aspects (hearing test functionality) of the BHA100 Series Braun® Clear™ Hearing Aid system, which can be considered a Type 4, air-conduction audiometer, per ANSI ASA S3.6:2018 - Specifications for Audiometers.

The design of the BHA100 Series Braun® Clear™ Hearing Aid system provides safe exposure to amplified sound to the individual user. To prevent the unlikely possibility of excessive exposure to high-level sound, hardware and software have been implemented to limit maximum sound output to 100 dB HL. The Braun® ClearCheck™ Hearing Test feature of the BHA100 Series Braun® Clear™ Hearing Aid system has been designed to conform to the following performance and safety standards:

- ANSI ASA S3.6:2018 - Specifications for Audiometers
  - Section 5.4.3 - Unwanted sounds from an earphone
  - Section 6.1.4 - Frequency accuracy
  - Section 6.1.5 - Harmonic Distortion
  - Applicable parts of Section 7.2 - Accuracy of sound pressure and vibratory force level for pure-tone and speech
  - Section 7.3.1 - Hearing level control increments
  - Section 7.3.3 - Hearing level control linearity
  - Section 7.5.3 - Rise / fall times for audiometers
- ANSI / AAMI / ES 60601-1:2012 – Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- 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

Similar performance between the Braun® ClearCheck™ Hearing Test feature of the BHA100 Series Braun® Clear™ Hearing Aid system and the iHearTest (K151025) is based on testing the Braun® ClearCheck™ Hearing Test feature using performance standard testing that was used to test the reference device, the iHearTest (K151025). Performance of the Braun® ClearCheck™ Hearing Test feature was also confirmed in the pivotal clinical validation study, during which the self-fitting feature of the BHA100 Series Braun® Clear™ Hearing Aid was compared to fitting by a licensed audiologist with a calibrated, clinical audiometer.

XIV. CONCLUSION

The BHA100 Series Braun® Clear™ Hearing Aid is substantially equivalent in intended use to the Bose SoundControl™ Hearing Aids (K211008). The non-clinical testing and performance data verify the safety and effectiveness of the subject device and the hardware and software verification and validation demonstrate that the BHA100 Series Braun® Clear™ Hearing Aid should perform as intended in the specified use conditions. The clinical data validates that the BHA100 Series Braun® Clear™ Hearing Aid performs comparably to the performance of the predicate device, the Bose SoundControl™ Hearing Aids, as outlined in K211008, which were cleared for marketing in the US in June 2021.

Therefore, the BHA100 Series Braun® Clear™ Hearing Aid is substantially equivalent to the predicate device, the Bose SoundControl™ Hearing Aids (K211008) and is considered as safe and effective for its intended use when used in accordance with its Instructions for Use.