September 25, 2023

Huizhou Jinghao Medical Technology Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co Ltd
Room 1407, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518000
China

Re: K221052
Trade/Device Name: Self-Fitting 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 21, 2023
Received: August 25, 2023

Dear Reanny Wang:

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)*
K221052

Device Name
Self-Fitting hearing aid

Indications for Use *(Describe)*

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

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

The assigned 510(k) number is: K221052

1.0 Information of Submitter and Correspondent

Submitter's information:

Company Name: Huizhou Jinghao Medical Technology CO., LTD.

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Submission correspondent information:

Company Name: Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

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Contact person: Reanny Wang

E-Mail: Reanny@reanny.com

2.0 510(k) Summary prepared date

September 1, 2023

3.0 Device Information

Trade Name: Self-Fitting hearing aid

Models: JH-D58

Common Name: Hearing aids

Classification Name: Self-Fitting Air-Conduction Hearing Aid Regulation

Description: Self-Fitting Air-Conduction Hearing Aid Regulation Medical

Specialty: Ear Nose & Throat

Product Code: QUH

Regulation Number: 21 CFR 874.3325

Device Class: 2

4.0 Predicate Device Information

Predicate device:

Sponsor: Bose Corporation

Device: Bose SoundControl Hearing Aids

510(K) Number: K211008

Reference device:

Sponsor: Kaz USA, Inc., a Helen of Troy Company

Device: BHA100 Series Braun Clear Hearing Aid

510(K) Number: K212609

5.0 Intended Use/Indications for use

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

6.0 Device Information

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

7.0 Labeling

The Self-Fitting hearing aid user manual including the following elements:

- Manufacturer Information
- Intended Use/Indications for use
- Directions for Use, including hearing aid and APP's operation
- Warnings and Precautions
- Specifications

The labeling is compliant with 21 CFR 800.30 (c) for OTC hearing aids, which includes information to help the user identify if they are a candidate for this device.

8.0 Special controls

The Self-Fitting Hearing Aid conforms to the special controls stated in 21 CFR 874.3325. These requirements were satisfied through the following:

- Clinical Validation
- Non-Clinical Performance Testing
- Usability Validation
- Labeling

9.0 Performance Summary

Performance data includes “Non-Clinical Data” and “Clinical Data”, as described below.

9.1 Non-Clinical Testing:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Self-Fitting hearing aids was conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process,” for an intact skin contacting device. The following tests were performed, and results demonstrate the biocompatibility of the subject device: Cytotoxicity, Skin Sensitization, Skin Irritation.

Electrical safety, Home Healthcare environment and electromagnetic compatibility (EMC)

Electrical safety, Home Healthcare environment and EMC testing were conducted, and the results show that the subject device complies with the IEC 60601-1: 2005+CORR. 1 (2006)+CORR. 2 (2007)+A1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance, 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, and the 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.

Bench Testing

Bench testing was conducted, and the results show that the subject device complies with the IEC 60601-2-66:2019 Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems and ANSI ASA S3.22-2014 American National Standard Specification of Hearing Aid Characteristics. The performance meets the requirements defined in IEC 60601-2-66 and ANSI ASA S3.22. The subject device also conforms to the applicable clauses of ANSI ASA S3.6: Specifications for Audiometers, similar to the BHA100 Series Braun® Clear™ Hearing Aid reference device.

Software Verification and Validation Testing

Software documentation including verification & validation was provided in accordance with FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a moderate level of concern.

Usability testing

The usability test included 20 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 with the Self-Fitting hearing aids, including the “JH Smart” APP, accessories, and user documentation including the labels and user manual. After the use scenarios and knowledge tasks, the participants completed subjective questionnaires about their use of the device. Results indicated that the Self-Fitting hearing aids are able to be used correctly by the intended users under anticipated conditions of use.

9.2 Clinical Testing:

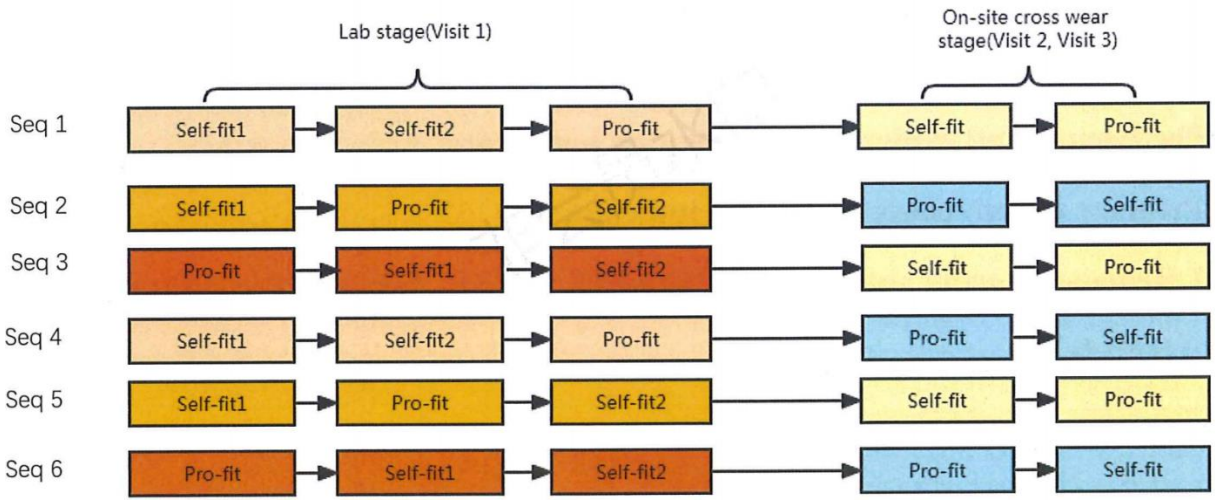
Clinical design and procedure:

A clinical study was conducted to verify the safety and effectiveness of the Self-fitting hearing aids (model JH-D58) and “JH Smart” APP in users with mild to moderate hearing impairment. This study was a prospective, randomized, cross-assigned, non-inferiority, multi-center clinical trial.

This study had two stages: laboratory and on-site cross wear field trial.

During the laboratory stage, participants completed in random order, the first self-adaptation (Self-fit1) and second self-adaptation (Self-fit2) procedures according to the instructions in the User Manual, and audiological best practice hearing aid fittings (Pro-fit).

During the field trial stage, a crossover design was used with each participant receiving two fitting strategies in random order (Pro-fit and Self-fit). Each wear cycle lasted 10-14 days. A flow chart of the two stages is shown below:



Sample size and subjects:

The sample size for this clinical study was determined by the main outcome measurement value, Abbreviated Profile of Hearing Aid Benefit (APHAB), of the field trial. The sample size estimation software is based on PASS 15.0 and requires a total of 32 samples, which means that the sample size for each sequence group in the crossover design stage is 16.

36 subjects who met the inclusion criteria were selected as the research subjects, and the study was conducted at two on-site centers (18 subjects per center). The study population is described in the table below:

Variables	Value	Total(n=36)	Self-Pro group	Pro-Self group	Chi-square	*P-value*
Age group	18~40	4(11.1)	2(11.1)	2(11.1)	-	0.594
	41~50	2(5.6)	2(11.1)	0(0.0)		
	51~60	9(25.0)	3(16.7)	6(33.3)		
	61~70	13(36.1)	6(33.3)	7(38.9)		
	≥71	8(22.2)	5(27.8)	3(16.7)		
Gender	Female	17(47.2)	11(61.1)	6(33.3)	2.786	0.095
	Male	19(52.8)	7(38.9)	12(66.7)		
History of hearing aid use	No	36(100.0)	18(100.0)	18(100.0)	0.000	1.000

Of the 36 subjects enrolled, 6 subjects withdrew due to poor compliance or personal reasons. This study was ultimately based on 30 subjects for analysis. Although the sample size of this clinical study did not reach the planned minimum of 32 subjects (due to subject withdrawal), the results from the remaining 30 subjects still demonstrate the effectiveness of the self-fitting strategy, albeit with slightly reduced statistical power.

Effectiveness analysis endpoints:

1) Co-Primary Endpoints:
   a) In the first stage of laboratory wearing, the Real Ear Aided Gain (REAG) in the Self-fit condition at four frequencies (500Hz, 1000Hz, 2000Hz, 4000Hz) in the left and right ears was not inferior to that in the Pro-fit condition with a non-inferiority margin of 2.5 dB.
   b) In the first stage of laboratory wearing, REAG (Self-fit 1 vs Self-fit 2) measurements were similar between the two Self-fit measurements.
   c) In the second stage of field trial wearing, the APHAB global rating of the Self-fit condition is not inferior to that of the Pro-fit condition with a non-inferiority margin of 0.084.

2) Secondary Endpoints:
   a) In the first stage of laboratory wearing, the speech recognition threshold in noise (SNR) in the Self-fit condition is not inferior to that of the Pro-fit condition.
   b) In the first stage of laboratory wearing, the speech recognition threshold in noise (Self-fit1 vs Self-fit2) is similar, and the results of the two Self-fit measurements are similar.
   c) In the second stage of field trial wearing, the speech recognition threshold in noise (Self-fit vs. Pro-fit), of the Self-fit condition is not inferior to that of the Pro-fit condition.

Safety Evaluation:

Record adverse events **(AE)** or serious adverse events **(SAE)** related to the test device.

Results:

Co-Primary Effectiveness Endpoints:

1. First co-primary endpoint: In the laboratory, the REAG (Self-fit1 vs Pro-fit) at four frequencies (500Hz, 1000Hz, 2000Hz, 4000Hz)

   Analysis results: The analysis of variance results of the 2×2 cross design showed that the estimated points of the difference in REAG between the two fitting conditions were between -2.5000 and 0.2799 at each frequency of the left and right ears. The 95% confidence intervals for the difference between the right ear conditions at 500Hz, 1000Hz, 2000Hz, and 4000Hz are (-1.7976，0.8933), (-2.6485，1.0217), (-1.0099，1.0003), (-1.6803，2.2401); the 95% confidence intervals for the difference between the left ear conditions at 500Hz, 1000Hz, 2000Hz, and 4000Hz are (-2.4308，0.5744), (-3.9191，0.6464), (-4.3019，-0.6981), (-2.3433, 2.3625). The non-inferiority margin of 2.5 and the upper limit of 95% confidence interval

between all parts and frequencies is less than the threshold of 2.5; The P values for the non-inferiority test between the two fitting conditions at different frequencies 500Hz, 1000Hz, 2000Hz, and 4000Hz in the left and right ears are: Right ear: P<0.0001, P=0.0005, P=<0.0001, P=0.0139; Left ear: P=<0.0001, P=0.0009, P=<0.0001, P=0.0194.

Figure 1 (below) shows the real-ear aided gain (REAG) for both fitting conditions (Self-fit and Pro-fit) across the frequency range (n = 30 subjects). Figure 1 shows that the two test conditions have similar REAG results.

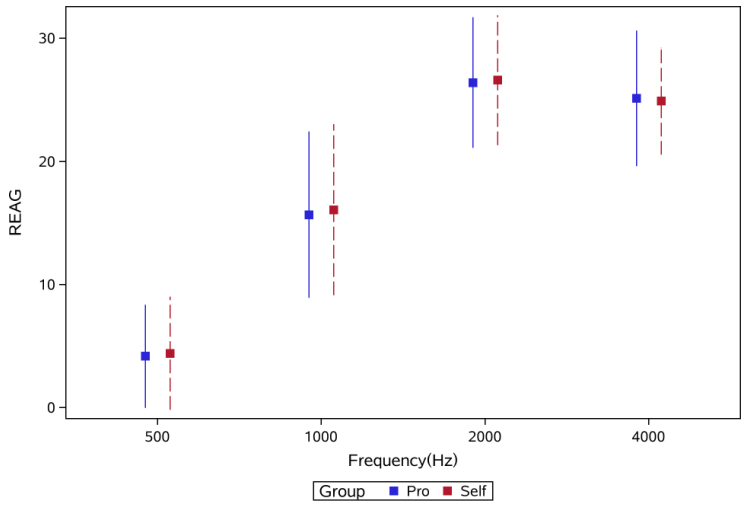


Figure 1: Error bar chart of REAG at 500, 1000, 2000, and 4000 Hz (mean ± standard deviation) for the Self-fit and Pro-fit conditions.

Conclusion: At the four frequencies (500Hz, 1000Hz, 2000Hz, 4000Hz) of the left and right ears, the laboratory REAG of the Self-fit condition was not inferior to the Pro-fit condition with a threshold of 2.5 dB.

2. Second co-primary endpoint: In the laboratory, REAG (Self-fit1 vs Self-fit2) measurements

Analysis results: The paired t-test results showed that at each frequency of the left and right ears, the estimated point difference between the two measurements of the Self-fit condition (Self-fit1-Self-fit2) REAG was between -0.4000 and 0.8667. The 95% confidence intervals for the difference between the two measurements of 500Hz, 1000Hz, 2000Hz, and 4000Hz in the right ear were (-1.0725，0.8725), (-0.6767，1.9434), (-1.9115，1.1115), (-1.1188，1.8522); the 95% confidence intervals for the difference between the two measurements of 500Hz, 1000Hz, 2000Hz, and 4000Hz in the left ear were (-1.5968，1.3302), (-0.5968，2.3302), (-0.4443，2.1777), (-1.8498，1.9831). The test statistics and P-values are shown in the table below:

Site	Frequency	Mean	Standard deviation	95% lower limit	95% upper limit	t value	P value
Right ear	500	-0.1000	2.6044	-1.0725	0.8725	-0.21	0.8349
Right ear	1000	0.6333	3.5084	-0.6767	1.9434	0.99	0.3310
Right ear	2000	-0.4000	4.0480	-1.9115	1.1115	-0.54	0.5925
Right ear	4000	0.3667	3.9782	-1.1188	1.8522	0.50	0.6175
Left ear	500	-0.1333	3.9193	-1.5968	1.3302	-0.19	0.8535
Left ear	1000	0.8667	3.9193	-0.5968	2.3302	1.21	0.2356
Left ear	2000	0.8667	3.5109	-0.4443	2.1777	1.35	0.1868
Left ear	4000	0.0667	5.1323	-1.8498	1.9831	0.07	0.9438

Conclusion: At the four frequencies (500Hz, 1000Hz, 2000Hz, 4000Hz) of the left and right ears, there was no statistically significant difference between the two measurements of the REAG for the Self-fit repeated measures in the laboratory, and the results of the two Self-fit measurements were similar.

3. Third co-primary endpoint: APHAB global rating (field trial)

Analysis results: The analysis of variance results of the 2×2 cross design showed that the point estimate of the APHAB difference between the two device groups in the on-site cross wearing test was 0.0109 (95%CI：-0.00951，0.0314). Using 0.084 as the non-inferiority threshold for non-inferiority testing, the 95% confidence interval (-0.00951~0.0314) of the difference between the global APHAB scores of the two devices was lower than the threshold value of 0.084 ($P<0.0001$).

Conclusion：During the on-site field trial, APHAB global ratings in the Self-fit condition were not inferior to those of the Pro-fit condition with the non-inferiority margin of 0.084.

Secondary Effectiveness Endpoints:

1. In-lab speech reception threshold in noise SNR (Pro-fit vs Self-fit1): The analysis of variance results of the 2×2 cross design showed that after considering stage effects, the difference in SNR between the two fitting conditions was 0.4450 (95%CI：-0.6703，1.5602). The correlation coefficients of speech recognition thresholds between the Self-fit1-Pro-fit condition and the Pro-fit-Self-fit1 condition were 0.83519 and 0.94816, respectively.
2. In-lab speech reception threshold in noise SNR (Self-fit1 vs Self-fit2)： The paired t-test analysis results showed that the difference between the two Self-fit measurements was

0.4000 (95%CI：-0.5020，1.3020). The correlation coefficient between the two measurements of speech recognition threshold was 0.91817.

3. On-site field trial speech reception threshold in noise SNR (Pro-fit vs Self-fit)：The analysis of variance results of the 2×2 cross design showed that after considering stage effects, the difference in SNR between the two fitting conditions was -0.1830（95%CI：-1.0473，0.6812). The correlation coefficients between the speech recognition thresholds of the Self-fit1-Pro-fit condition and the Pro-fit-Self-fit1 condition were 0.92112， 0.92365, respectively.

The confidence intervals for the secondary endpoints are at their nominal level without adjusting for the multiplicity issue.

Safety Evaluation:

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

Study Conclusions

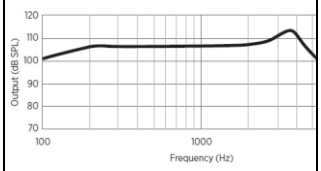
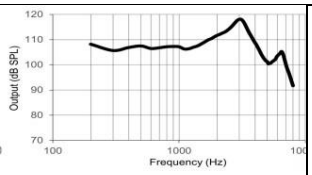
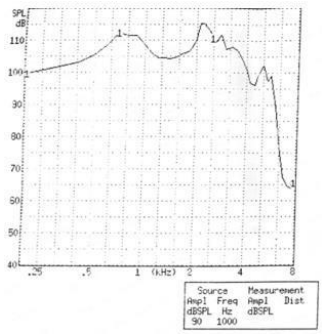
The clinical data from this study demonstrates the effectiveness of the self-fitting strategy and satisfies the special controls for the self-fitting hearing aids regulation. Participants experienced non-inferior outcomes with self-fitting compared to professional fitting of the subject device.

10.0 Comparison to predicate device

The subject device Self-Fitting hearing aid has similar indications for use and technological characteristics as the predicate device Bose SoundControl Hearing Aids (K211008) and reference device BHA100 Series Braun Clear Hearing Aid (K212609). They are all self-fitting hearing aids indicated for individuals 18 and older with perceived mild to moderate hearing impairment. The same fundamental technology is present in these three hearing aids to allow the user to control and customize the device to the user's hearing needs. The table below provides an overview comparison of the subject, predicate, and reference devices:

Elements of Comparison	**Predicate Device (K211008)**	**Reference Device (K212609)**	**Subject Device**	**Comparison**
Models	BMD0012	BHA100 series	JH-D58	--

Company	Bose Corporation	Kaz USA, Inc., a Helen of Troy Company	Huizhou Jinghao Medical Technology Co., Ltd.	--
Device Name	Bose SoundControl Hearing Aids	BHA100 Series Braun Clear Hearing Aid	Self-Fitting Hearing Aid	--
Product code	QDD	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 21 CFR 800.30 for OTC hearing aids.
Regulation #	21CFR874.3325	21 CFR 874.3325	21CFR874.3325	Same
Intended use	The Bose SoundControl™ Hearing Aids is 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. No preprogramming 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 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 Self-Fitting hearing aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. They are adjusted by the user to meet the user's hearing needs. The device is intended for use without the assistance of a hearing care professional.	The 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.
Type	BTE	BTE	BTE	Same
Patient Population	18 years and older	18 years and older	18 years and older	Same
Sound mode	Air conduction	Air conduction	Air conduction	Same

OSPL90 Curve				Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.
Max OSPL90	113 dBSPL	120 dBSPL	117dBSPL	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence. The Max output does not exceed 117dB SPL at any frequency and is therefore compliant with 21CFR800.30 requirements for OTC hearing aids.
HFA OSPL90	106 dBSPL	111±2 dBSPL	<108dB±4dB	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.
HFA FOG	30 dB	40±2 dB	<35dB±5dB	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.
RTG	29 dB	34+/-4 dB	33 dB	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.
Frequency range	<200-8000 Hz	200 Hz to 8000 Hz	250~5000Hz (Not narrower than)	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence. The frequency range is at least 250-5000Hz and is therefore compliant with 21CFR800.30 requirements for OTC hearing aids.

Harmonic Distortion	<1%	500 Hz ≤ 1.5% 800 Hz ≤ 2.0% 600 Hz ≤ 3.0%	＜ 0.4%+3%	The distortion does not exceed 5% and is therefore compliant with 21CFR800.30 requirements for OTC hearing aids.
EIN	<27 dBSPL	＜29dB SPL	≤ 32dBSPL	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence. The EIN does not exceed 32dB and is therefore compliant with 21CFR800.30 requirements for OTC hearing aids.
Attack Time	--	--	700ms±50%	--
Release Time	--	--	700ms±50%	--
Latency	--	--	≤ 14ms	-- The latency does not exceed 15ms and is therefore compliant with 21CFR800.30 requirements for OTC hearing aids.
Battery current drain	2.8mA	2.5mA	< 10mA	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.
Power supply	DC 1.45V, Size 312 Battery	DC 1.45V, #312 zinc air batteries	DC 3.7V / 45mAh Rechargeable Li-ion battery	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.
Technological characteristics	• Self-Fitting Hearing Aid •Home Healthcare Environment Use • Bluetooth • On Device Controls • App (Bose Hear app) • Software Platform Compatibility (iOS, Android)	• Self-Fitting Hearing Aid • Home Healthcare Environment Use • Bluetooth • On Device Controls • App (Braun® Clear™ App) • Software Platform	• Self-Fitting Hearing Aid • Home Healthcare Environment Use • Bluetooth • On Device Controls • App (JH Smart APP) • Software Platform Compatibility (iOS, Android)	Performance testing was conducted to evaluate differences in technology and the results support substantial equivalence.

	• RIC style hearing aid • A Replaceable Battery	Compatibility (iOS, Android) • Replaceable, Disposable, 1.45 Volt, Size 312, Zinc Air Hearing Aid Battery • Traditional, Receiver-In- Canal (RIC) / Behind- The-Ear (BTE) Form Factor • Self-administered hearing test	• Rechargeable Li-ion battery • Traditional, Receiver-In-Canal (RIC) / Behind-The-Ear (BTE) Form Factor • Self-administered hearing test	
Degree of protection against electric shock	Type B applied part	Unknown	Type B applied part	Same
Type of protection against electric shock	Internally power equipment	Internally power equipment	Internally power equipment	Same
Model of Operation	Continuous operation	Continuous operation	Continuous operation	Same
Performance	Compliance with Compliance with IEC 60601-2-66:2019 ANSI/ASA S3.22 2014	Compliance with Compliance IEC 60601-2-66:2019 ANSI/ASA S3.22 2014 ANSI CTA 2051:2017	Compliance with Compliance IEC 60601-2-66:2019 ANSI/ASA S3.22 2014 ANSI CTA 2051:2017	Same
Safety	Compliance with Compliance with IEC 60601- 1:2005+A1:2012 IEC 60601-1-11:2015 IEC 60601-1-2:2014	Compliance with Compliance with IEC 60601- 1:2005 +A1:2012 IEC 60601-1-11:2015 IEC 60601-1-2:2014	Compliance with Compliance with IEC 60601-1:2005+A1:2012 IEC 60601-1-11:2015 IEC 60601-1-2:2014	Same
Material	ABS housing and ABS keys	ABS housing and ABS keys	ABS housing and ABS keys	Same

Biocompatibility	All the patient contacting materials are compliance with ISO 10993	All the patient contacting materials are compliance with ISO 10993	All the patient contacting materials are compliance with ISO 10993	Same

As seen in the comparison tables, the subject and predicate devices have same design principle, similar design features and performance specifications. The different technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness. The subject and predicate devices have some relatively minor differences in their electroacoustic characteristics (e.g., MaxOSPL90, HFA FOG) and a different battery type; however, clinical testing demonstrated reasonably safe and effective outcomes that are appropriate for the intended use population, similar to the predicate device.

11.0 Conclusion

The Self-Fitting hearing aid is 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. The Self-Fitting hearing aid has similar indications, technological characteristics, and performance characteristics as the Bose SoundControl predicate device. Non-clinical testing and clinical testing were conducted on the subject device and all testing passed pre-specified criteria. Any minor differences between the subject and predicate devices have been addressed through the performance testing. The risks of the Self-Fitting hearing aid also have been evaluated according to ISO 14971, and the overall residual risk are acceptable. In conclusion, the subject device is as safe and effective, and performs as well as, the legally marketed predicate device predicate. The Self-Fitting hearing aid meets the special controls for self-fitting hearing aids outlined in 21 CFR 874.3325.