August 19, 2026

Shokz Health Global Limited
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Rm. 1509, Jingting Bldg., Dongzhou Community,
Guangming St., Guangming
Shenzhen, Guangdong 518100
China

Re: K253431
Trade/Device Name: Bone conduction Hearing Aid (BM100, SHOKZHEAR BM400, SHOKZ BM400MN, SHOKZHEAR BM410, SHOKZHEAR BM410MN, SHOKZHEAR BM420 and SHOKZHEAR BM420MN)
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: July 6, 2026
Received: July 6, 2026

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn

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

Sincerely,

SHUCHEN PENG -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253431

Please provide the device trade name(s).

Bone conduction Hearing Aid (BM100, SHOKZHEAR BM400, SHOKZ BM400MN, SHOKZHEAR BM410, SHOKZHEAR BM410MN, SHOKZHEAR BM420 and SHOKZHEAR BM420MN)

Please provide your Indications for Use below.

The device is intended to treat patients with hearing loss via bone conduction. The device is non-invasive bone conduction hearing device which is retained on the patient's head.

Indications:
1)Patients above 6 years old with conductive or mixed hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL.
2)Patients 18 years and older with sensorineural hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

The assigned 510(k) number is: K253431

1.0 Information of Submitter and Correspondent

Submitter's information:

Company Name: Shokz Health Global Limited

Street Address: ROOM 708, 7TH FLOOR, HANG SENG CASTLE PEAK ROAD BUILDING, 339 CASTLE PEAK ROAD, CHEUNG SHA WAN, KOWLOON

City: HONG KONG

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Contact Person: Guihong Dai

Contact Title: RA Manager

Consultant's information

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

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Contact Person: Reanny Wang

Contact Title: General Manager

Contact Email: reanny@reanny.com

2.0 510(k) Summary prepared date

August 18, 2026

3.0 Device Information

Trade Name:	Bone conduction hearing aid
Models:	BM100, SHOKZHEAR BM400, SHOKZ BM400MN, SHOKZHEAR BM410, SHOKZHEAR BM410MN, SHOKZHEAR BM420 and SHOKZHEAR BM420MN
Common Name:	Bone conduction hearing aid
Classification Name:	Hearing aid, bone conduction
Regulation Description:	Bone-conduction hearing aid

Regulation Medical Specialty:	Ear Nose & Throat
Review Panel:	Ear Nose & Throat
Regulation Number:	LXB, 874.3302
Device Class:	2

4.0 Predicate Device Information

Predicate device:

Sponsor: Cochlear Americas

Device: Baha 5 Power Sound Processor

510(K) Number: K161123

Reference device:

Sponsor: Cochlear Americas

Device: Cochlear Baha® SoundArc

510(K) Number: K171088

5.0 Intended Use/Indications for use

The device is intended to treat patients with hearing loss via bone conduction. The device is non-invasive bone conduction hearing device which is retained on the patient's head.

Indications:

1) Patients above 6 years old with conductive or mixed hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL.

2) Patients 18 years and older with sensorineural hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL.

6.0 Device Information

The Bone conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that conducts sound to the inner ear through the skull. The device is non-sterile and non-implanted device. The Bone conduction hearing aid is worn over the condyle in front of the auricle and converts acoustic sound into mechanical vibrations. The vibrations are transmitted through the skin and skull to the inner ear to stimulate the cochlea.

The device is a prescription hearing aid intended to be fitted by audiologists or other hearing healthcare professionals. The ShokzHear Fit hearing aid fitting software is used to program and fit

the hearing aids and supports programming of the hearing aids for the left and right ears individually to enable bilateral fitting. The fitting software allows the hearing care professional to enter the patient's audiogram to establish the initial fitting settings and subsequently fine-tune the hearing aids based on patient feedback.

The BM100, SHOKZHEAR BM400, SHOKZ BM400MN, SHOKZHEAR BM410, SHOKZHEAR BM410MN, SHOKZHEAR BM420 and SHOKZHEAR BM420MN are bone conduction hearing aids, suitable for patients with conductive, mixed and sensorineural hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL.

7.0 Comparison to predicate device

The subject device has similar indications for use and technological characteristics as the predicate device Baha 5 Power Sound Processor (K161123). They are all Bone conduction hearing aids indicated for patients with conductive hearing loss, mixed hearing loss and sensorineural hearing loss. The table below provides an overview comparison of the subject, predicate, and reference device:

Device	Subject device	Primary Predicate device	Reference device	Comparison
Manufacturer	Shokz Health Global Limited.	Cochlear Americas	Cochlear Americas	/
510(K) number	K253431	K161123	K171088	/
Product name	Bone conduction Hearing Aid	Baha 5 Power Sound Processor	Cochlear Baha® SoundArc	/
Classification	Class II Device, LXB (21 CFR 874.3302)	Class II Device, LXB (21 CFR 874.3302)	Class II Device, LXB (21 CFR 874.3302)	Same
Patient Population	Patients above 6 years old with conductive or mixed hearing loss; Patients above 18 years old with sensorineural hearing loss.	Patients aged 5 and older with hearing loss	Any age patients who cannot or choose not to have an implant	Supporting SE between the subject and predicate device， see Comment 1
Environment of use	Indoor and outdoor	Indoor and outdoor	Indoor and outdoor	Same
Indications for Use (IFU)	The device is intended to treat patients with hearing loss via bone conduction. The device is non-invasive bone conduction hearing device which is retained on the patient's head. Indications: 1) Patients above 6 years old with conductive or mixed hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL. 2) Patients 18 years and older with sensorineural hearing loss. The pure tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL.	The Cochlear Baha® 5 Power Sound Processor is intended for the following patients and indications for use: *Patient of any age for use with the Baha Softband or headband. Patients aged 5 and older for use with the Baha auditory osseointegrated implant system. *Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 55 dB HL. *Bilateral fitting is intended	The Cochlear Baha® SoundArc is intended for test situations and for patients who cannot or choose not to have an implant for the following indications for use: • Patients of any age who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3kHz) should be better than or equal to 45 dB HL for use with the BP100, Baha 4 and Baha 5 sound processors, 55 dB HL for use with the BP110 Power and Baha 5 Power sound processors, and better than	Supporting SE between the subject and predicate device, see Comment 1

Device	Subject device	Primary Predicate device	Reference device	Comparison
		for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies. *Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single sided deadness: SSD). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL. *Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.	or equal to 65 dB HL for use with the Cordelle II and Baha 5 SuperPower Sound Processors. • Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conductive thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1,2, and 3 kHz), or less than a 15dB difference at individual frequencies. • Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. Single sided deafness: SSDTM). Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL. • Baha for SSD is also indicated for any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason	

Device	Subject device		Primary Predicate device	Reference device	Comparison
				cannot or will not use an AC CROS.	
OTC or Rx	Rx		Rx	Rx	Same
Exterior design	Bone conduction hearing aids adopt a rear-hanging sinking structure to place the bone guide oscillator at the temporal bone in front of the ear		LED, program button, volume rocker, and battery door (which can be replaced with tamper resistant door)	Baha SoundArc is an encapsulated spring wire that wraps around the back of the head and sits behind and above the ears.	SE, the predicate device can be used as non-implantable device when it loads onto the SoundArc.
Materials	Silicone and PC that have been shown to be biocompatible and safe for human use		Made of medical grade plastics and metals that have been shown to be biocompatible and safe for human use	• Silopren LSR 4040 • Grilamid L 25 (polyamide) Natural 6112	SE, the material difference do not raise different questions of safety and effectiveness to the predicate device.
Maximum OVFL90/dB rel.1μN	**BM100**	**BM420 series**	123	SoundArc transfers vibrations from the sound processor to the mastoid through the skin, without the need for surgery. SoundArc has the same intended use as the currently cleared Baha system, and the same fundamental operating principles and functional characteristics as the existing non-surgical bone conduction headband and Softband for Baha. The existing cleared range of Baha sound processors attach to the SoundArc in the same manner as the predicate device, through snap coupling. /	Supporting SE between the subject and predicate device, see Comment 2
	123	125			
HFA-OVFL90/dB rel.1μN	115	115	113		
Full-on HFA-AMSL/dB	35	46	Unknown		
Maximum full-on AMSL/dB	40	53	49		
Equivalent input noise/dB SPL	＜28	＜22	26		
Frequency range/Hz	f1<200 f2>4000	f1<200, f2>6000	250~7000		
Total harmonic distortion @ 500Hz	＜1%	＜2%	3%		
Total harmonic	＜1%	＜1%	3%		

Device	Subject device		Primary Predicate device	Reference device	Comparison
distortion @ 800Hz					
Total harmonic distortion @ 1600Hz	＜1%	＜1%	3%		
Total harmonic distortion @ 3200Hz	＜1%	＜1%	3%		
Battery size and type	3.8V/170mAh Lithium-ion battery	DC 3.87V / 235mAh lithium-ion battery	675 (zinc-air)	/	SE, the battery difference will not raise different questions of safety and effectiveness to the predicate device.

Bone conduction hearing aid (including models of BM100, SHOKZHEAR BM400, SHOKZ BM400MN, SHOKZHEAR BM410, SHOKZHEAR BM410MN, SHOKZHEAR BM420 and SHOKZHEAR BM420MN) have the same intended use, working/technical principle, and structure as those of the predicate device, Baha 5 Power Sound Processor. The main differences lie in the power supply, size and specifications. BM100 was selected as representative device since it has the smallest frequency range, Full-on HFA-AMSL/dB, Maximum Full-on AMSL/dB and represented the worst-case scenario.

The subject device Bone conduction hearing aid is a non-implanted device. The predicate device Baha 5 Power Sound Processor (K161123) cannot be used for hearing compensation in a non-implantable manner when it use alone. The reference device, the Cochlear Baha® SoundArc (K171088), is a spring wire worn behind the ear and over the head posteriorly. It should be noted that SoundArc alone cannot provide hearing amplification. When a sound processor is loaded onto the disc mount on this spring wire, it forms a complete non-implantable hearing system. Therefore, the Baha 5 Power Sound Processor is selected as the predicate device and the Cochlear Baha® SoundArc as the reference device, considering the combination as a complete non-implantable hearing system.

Comment 1:

The subject device and predicate device are indicated for patients with conductive hearing loss and mixed hearing loss. The subject device differs from the predicate device in terms of patient population age, sensorineural hearing loss indication, and hearing threshold. A clinical trial was conducted with the subject device in patients with conductive, mixed and sensorineural hearing loss with hearing thresholds within 60 dB HL at 0.5, 1, 2, and 4 kHz. Therefore, these differences will not raise issue of safety and effectiveness.

Comment 2:

The Maximum OVFL90, HFA-OVFL90, Full-on HFA-AMSL, Maximum full-on AMSL and Equivalent input noise are similar with predicate device; the frequency range and total harmonic distortion are within the range of predicate device. Performance testing (including IEC 60118-9 standard testing and output curves comparison) and clinical literature analysis demonstrated that these differences do not raise concerns of safety and effectiveness.

8.0 Performance Summary

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

8.1 Non-Clinical Testing:

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

Biocompatibility testing

The biocompatibility evaluation for the Bone conduction hearing aids was conducted in accordance with FDA guidance: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

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 IEC60601-1:2005+ AMD1:2012+AMD2:2020 Medical electrical equipment Part 1: General requirements for basic safety and essential performance, IEC 60601-1-11: 2020 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: 2020 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 per IEC 60118-9, Electroacoustics – Hearing aids – Part 9: Methods of measurement of the performance characteristics of bone conduction hearing aids. The performance meets the requirements defined in that standard.

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 40 untrained participants representing the intended user population, each of whom performed hands-on use scenarios and knowledge tasks with the Bone conduction hearing aids, 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 Bone conduction hearing aids are able to be used correctly by the intended users under anticipated conditions of use.

8.2 Clinical Testing:

Clinical design and procedure:

A clinical study was conducted to verify the safety and effectiveness of the Bone conduction hearing aids in users with conductive, mixed and sensorineural hearing loss and the hearing threshold (measured at 0.5, 1, 2, and 4kHz) should be better than or equal to 60 dB HL. This study was designed as a prospective, multicenter, self-controlled, open-label, single-arm study with objective performance criteria.

Sample size and subjects:

The sample size required for this clinical trial was 45 subjects per group, considering the possibility of dropout or serious protocol deviation of about 10% during the clinical trial. Therefore, at least 50 subjects with conductive or/and mixed hearing loss and 50 subjects with sensorineural hearing loss (total 100 subjects) were enrolled in this clinical trial.

Effectiveness analysis endpoints:

1) Primary effectiveness Endpoints:

The Primary effectiveness Endpoints is defined as meeting the following criteria:

a. when the subject wears the investigational device for 14 days ± 2 d, the functional gain of hearing aids is > 10dB as determined by binaural pure tone sound field audiometry;

b. binaural monosyllabic speech recognition rate is ≥ 20% improvement compared with that before wearing the investigational device under the specified sound intensity as determined by speech sound field audiometry in a quiet environment.

2) Secondary Endpoints:
   a. Speech recognition threshold level
   b. Hearing threshold level
   c. IOI-HA scale
   d. Device performance evaluation

Safety Evaluation:

a) Incidence of AEs

b) Incidence of device deficiencies

Results:

A total of 114 subjects were screened in this clinical trial, and 111 subjects were ultimately enrolled; three subjects were excluded due to not meeting the inclusion criteria. Of the 111 subjects enrolled, 109 subjects completed the trial. Among the enrolled, 61 (55.0%) had conductive or/and mixed hearing loss, and 50 (45.0%) had sensorineural hearing loss. All 111 subjects were included in the full analysis set (FAS), and 107 subjects were included in the per protocol set (PPS).

Primary effectiveness endpoints result:

FAS for the subject population:

Among subjects with conductive and mixed hearing loss, 59 achieved a functional gain of >10 dB in binaural pure-tone sound field testing after wearing the bone conduction hearing aid compared to before wearing it, accounting for 96.7% of the total enrolled subjects; in a quiet environment, 60 subjects showed an improvement of ≥20% in binaural monosyllabic speech recognition score

after wearing the investigational device compared to before wearing it, accounting for 98.4% of the total enrolled subjects.

Among subjects with sensorineural hearing loss, 46 achieved a functional gain of >10 dB in binaural pure-tone sound field testing after wearing the bone conduction hearing aid compared to before wearing it, accounting for 92.0% of the total enrolled subjects; in a quiet environment, 45 subjects showed an improvement of ≥20% in binaural monosyllabic speech recognition score after wearing the investigational device compared to before wearing it, accounting for 90.0% of the total enrolled subjects.

PPS for the subject population:

Among subjects with conductive and mixed hearing loss, 58 subjects with conductive or mixed hearing loss achieved a functional gain >10 dB in binaural pure-tone sound-field audiometry after wearing the bone conduction hearing aid compared to before wearing it, accounting for 96.7% of the total enrolled subjects; 60 subjects achieved an improvement of ≥20% in binaural monosyllable speech recognition score in a quiet environment compared to before wearing the investigational device, accounting for 100.0% of the total enrolled subjects.

Among subjects with sensorineural hearing loss,46 subjects with sensorineural hearing loss achieved a functional gain >10 dB in binaural pure-tone sound-field audiometry after wearing the bone conduction hearing aid compared to before wearing it, accounting for 92.0% of the total enrolled subjects; 45 subjects achieved an improvement of ≥20% in binaural monosyllable speech recognition score in a quiet environment compared to before wearing the investigational device, accounting for 90.0% of the total enrolled subjects.

The statistical analysis results showed that, for both the overall analysis and subgroup analyses, the results based on the FAS and those based on the PPS were similar. The Functional Gain and Improvement in Speech Recognition Score for overall and subgroup of the investigational medical device were both met the pre-specified target values, indicating that the investigational medical device met its claimed clinical intended use, was clinically acceptable, and had significant clinical application value for hearing compensation in patients with hearing loss due to conductive hearing loss, mixed hearing loss, or sensorineural hearing loss.

Secondary effectiveness endpoints

a) Hearing threshold level

FAS for the subject population:

Among subjects with conductive and mixed hearing loss, the baseline (before wearing the

investigational medical device) average hearing threshold (PTA4) was 58.8 ± 9.37 dB HL; the average hearing threshold (PTA4) at 14 ± 2 days after wearing the investigational medical device was 38.7 ± 6.47 dB HL.

Among subjects with sensorineural hearing loss, the baseline (before wearing the investigational medical device) average hearing threshold (PTA4) was 52.1 ± 4.90 dB HL; the average hearing threshold (PTA4) at 14 ± 2 days after wearing the investigational medical device was 38.1 ± 4.22 dB HL.

PPS for the subject population:

Among subjects with conductive and mixed hearing loss, the baseline (before wearing the investigational medical device) average hearing threshold (PTA4) was 58.8 ± 9.45 dB HL; the average hearing threshold (PTA4) at 14 ± 2 days after wearing the investigational medical device was 38.7 ± 6.47 dB HL, with a statistically significant difference compared to before wearing ($P < 0.0001$).

Among subjects with sensorineural hearing loss, the baseline (before wearing the investigational medical device) average hearing threshold (PTA4) was 52.2 ± 4.98 dB HL; the average hearing threshold (PTA4) at 14 ± 2 days after wearing the investigational medical device was 37.9 ± 4.19 dB HL.

The results indicated that the investigational medical device was effective in reducing the hearing threshold level in patients with conductive and mixed hearing loss and sensorineural hearing loss, providing amplification to improve audibility from their unaided hearing level.

b) Speech recognition threshold level

FAS for the subject population:

Among subjects with conductive and mixed hearing loss, the baseline (prior to wearing the investigational device) speech recognition threshold level (Mean±SD) was 52.3±8.58 dB HL. At Day 14±2 of wearing the investigational device, the speech recognition threshold level was 34.0±6.14 dB HL.

Among subjects with sensorineural hearing loss, the baseline (prior to wearing the investigational device) speech recognition threshold level (Mean±SD) was 42.4±9.90 dB HL. At Day 14±2 of wearing the investigational device, the speech recognition threshold level was 33.0±6.18 dB HL

PPS for the subject population:

Among subjects with conductive and mixed hearing loss, the baseline (prior to wearing the

investigational device) speech recognition threshold level (Mean±SD) was 52.5±8.53 dB HL. At Day 14±2 of wearing the investigational device, the speech recognition threshold level was 34.0±6.14 dB HL.

Among subjects with sensorineural hearing loss, the baseline (prior to wearing the investigational device) speech recognition threshold level (Mean±SD) was 42.5±10.08 dB HL. At Day 14±2 of wearing the investigational device, the speech recognition threshold level was 33.1±6.21 dB HL

The statistical analysis results indicated that the investigational medical device significantly improved the speech recognition level of the subjects with conductive and mixed hearing loss and sensorineural hearing loss.

c) IOI-HA scale

FAS for the subject population:

Among subjects with conductive and mixed hearing loss, 95% (58/61) of subjects considered that wearing the investigational medical device provided moderate, a lot, or very much help for their hearing. 96.8% (59/61) of subjects considered that wearing the investigational medical device was of moderate value, a lot of value, or very much value.

Among subjects with sensorineural hearing loss, 88.0% (44/50) of subjects considered that wearing the investigational medical device provided moderate, a lot, or very much help for their hearing. 94.0% (47/50) of subjects considered that wearing the investigational medical device was of moderate value, a lot of value, or very much value

PPS for the subject population:

Among subjects with conductive and mixed hearing loss,96.6% (58/60) of subjects considered that wearing the investigational medical device provided moderate, a lot, or very much help for their hearing.98.4% (59/60) of subjects considered that wearing the investigational medical device was of moderate value, a lot of value, or very much value.

Among subjects with sensorineural hearing loss, 91.5% (43/47) of subjects considered that wearing the investigational medical device provided moderate, a lot, or very much help for their hearing. 98.0% (46/47) of subjects considered that wearing the investigational medical device was of moderate value, a lot of value, or very much value

Statistical analysis results showed that over 80% of subjects considered that wearing the investigational medical device provided moderate, a lot, or very much help for their hearing, over 90% of subjects considered that wearing the investigational medical device was of moderate value, a lot of value, or very much value, and the majority of subjects considered that after using the investigational medical device, their quality of life was improved.

d) Device performance evaluation

The device performance evaluation was depended on subjective experience via finished questionnaire "Device performance evaluation form"

FAS for the subject population:

After wearing the investigational device, 91.0% were satisfied with the complete assembly and secure fixation of all components of the investigational device; 94.6% were satisfied with the clarity and correctness of the text, symbols, or markings on the investigational device; 96.4% were satisfied with the absence of defects such as burrs, flash, dents, or scratches on the surface of the investigational device; 81.1% were satisfied that the investigational device conformed to the natural contour of the ear and fitted well against the head; 73.9% were satisfied with the sound quality of the investigational device; 91.0% were satisfied with the battery operating time of the investigational device; 85.6% were satisfied with the volume adjustment of the investigational device.

PPS for the subject population:

After wearing the investigational device, 92.5% were satisfied with the complete assembly and secure fixation of all components of the investigational device; 96.3% were satisfied with the clarity and correctness of the text, symbols, or markings on the investigational device; 98.1% were satisfied with the absence of defects such as burrs, flash, dents, or scratches on the surface of the investigational device; 82.2% were satisfied that the investigational device conformed to the natural contour of the ear and fitted well against the head; 75.7% were satisfied with the sound quality of the investigational device; 93.5% were satisfied with the battery operating time of the investigational device; 87.9% were satisfied with the volume adjustment of the investigational device;.

Statistical analysis results showed that most subjects were satisfied with the evaluation results of the various performances of the investigational medical device, indicating that the investigational medical device had satisfactory usability and performance, and could achieve its claimed clinical intended use.

Safety Evaluation:

The adverse events percentages was out of the total sample size 61 for conductive and mixed hearing loss and 50 for sensorineural hearing loss.

No serious adverse events happened in this study and 8.2% (5/61) minor adverse events and 4.9% (3/61) minor adverse reactions found for subjects with conductive and mixed hearing loss;

and 2.0% (1/50) minor adverse events and 2.0% (1/50) minor adverse reactions found for subjects with sensorineural hearing loss, all of AEs disappeared or recovered without sequelae. All subjects continued to use the investigational device and completed the clinical trial. The incidence of device deficiencies was 1.60% (1/61) reported for subjects with conductive and mixed hearing loss and 2.0% (1/50) for subjects with sensorineural hearing loss, but the device deficiencies did not cause harm to the subjects and did not lead to adverse events.

Definition of adverse events: Any untoward medical occurrence occurred during clinical trial, regardless of relationship with the device.

Minor adverse events: adverse events require little or no treatment and do not affect the daily activities of subjects.

Study Conclusions

The Bone conduction hearing aid was safety and effective to hearing compensation in hearing loss patients with conductive hearing loss, mixed hearing loss and sensorineural hearing loss.

9.0 Conclusion

The Bone conduction hearing aid is intended to amplify sound for individuals above 6 years with conductive hearing loss, mixed hearing loss and 18 years and older sensorineural hearing loss. The Bone conduction hearing aid has similar indications, technological characteristics, and performance characteristics as the predicate device. Non-clinical testing and clinical testing were conducted on the subject device and all testing passed pre-specified criteria. The risks of the Bone conduction hearing aid also have been evaluated according to ISO 14971, and the overall residual risk are acceptable. In conclusion, technological differences between the Shokz (BM100 and SHOKZHEAR BM420 series) devices and their predicate device are addressed by the performance testing described above and do not introduce different questions of safety or effectiveness. Therefore, we can conclude that these devices are substantially equivalent.