June 11, 2026

Shenzhen Magnet Technology Co., Ltd.
% Riley Chen
RA specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm.2401 Zhenye International Business Center, # 3101-90, Qianhai Rd.
Shenzhen, Guangdong 518052
China

Re: K261256
Trade/Device Name: Bone Conduction Hearing Aid (XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3)
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: April 16, 2026
Received: April 16, 2026

Dear Riley Chen:

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.	K261256

Please provide the device trade name(s).

Bone Conduction Hearing Aid (XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3)

Please provide your Indications for Use below.

Bone Conduction Hearing Aid (models: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3) is wearable sound-amplifying device intended to compensate impairments in personal hearing. The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person. The amplification suits the needs of a mild to a moderate hearing loss. They require individual fitting in performance executed by a hearing aid professional. The device is intended for adults and children (≥12 years).

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary-K261256

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

Shenzhen Magnet Technology Co., Ltd
No.901, Building 9 of Zhongyuntai Industrial Park, Songbai Rd., Tangtou Community, Shiyan St., Bao'an Dist., Shenzhen, China
Post code: 518108
Fax: +86 0755-82598747

Xiangshun Tian
Title: Engineer
Tel.: +86 - 13699780460
Email: 51683858@qq.com

Date of preparation: 2026-6-02

II. Device Information

Name of Device: Bone Conduction Hearing Aid
Models: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3
Common or Usual Name: Hearing aid, bone conduction
Regulation Description: Bone-conduction hearing aid
Regulatory Class: II
Product Code: LXB
Regulation Number: 21 CFR 874.3302

III. Predicate Device

Predicate Device	Manufacturer	510(k) Number	Product code
Bone conduction hearing aid	BHM-Tech	K121793	LXB

IV. Device Description

The bone conduction hearing aid is intended as hearing compensation of bone conduction hearing loss patient. The intended operator is the patient (adults and children ≥12 years) with mild to a moderate hearing loss. No special skill, training or knowledge is required; the operator needs to read and follow the instruction manual. The device is intended to be used in home healthcare environment and public environment such as office. Hearing aid is made up of a bone conduction (output) transducer, control box (including an input transducer and a signal conditioning unit), battery (an internal rechargeable lithium-ion polymer battery), and headband (with built-in wiring).

The hearing aid can connect with the mobile phone through Bluetooth, the Bluetooth version is 5.3. Mobile devices used by users must support Bluetooth 4.2 or above.

V. Indications for Use

Bone Conduction Hearing Aid (models: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3) is wearable sound-amplifying device intended to compensate impairments in personal hearing. The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person. The amplification suits the needs of a mild to a moderate hearing loss. They require individual fitting in performance executed by a hearing aid professional. The device is intended for adults and children (≥12 years).

VI. Comparison of Technological Characteristics With the Predicate Device

The Bone Conduction Hearing Aid (models: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3) has the same intended use as the predicate device. The technological characteristics, features, specifications, design are similar to the predicate device. Any minor differences between the subject device and the listed predicate device do no raise any issues of safety or efficacy. Performance data supports that the device is substantially equivalent to the predicate device for its intended use.

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
K number	**K261256**	**K121793**	/
Trade name	Bone Conduction Hearing Aid	Bone conduction hearing aid	/
Model	XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3	An Evo1	/
Regulation number	874.3302	874.3302	Same
Device class	Class II	Class II	Same
Product code	LXB	LXB	Same
Indication for use/ Intended use	Bone Conduction Hearing Aid (models: XTS-AISW-D1, XTS-AISW-D2, XTS-AISW-D3) is wearable sound-amplifying device intended to compensate impairments in personal hearing. The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person. The amplification suits the needs of a mild to a moderate hearing loss. They require individual fitting in performance executed by a hearing aid professional. The device is intended for adults and children (≥12 years).	Bone conduction hearing aids by BHM-Tech are wearable soundamplifying devices intended to compensate impairments in personal hearing. The fundamental operating principle is to receive, amplify, and transfer sound via the skin and the bone of the skull to the inner ear of a hearing impaired person. The amplification suits the needs of a mild to a moderate hearing loss. They require individual fitting in performance executed by a hearing aid professional. The target populations for the devices are as follows: AN-Evo1: adults and children (≥12 years)	Same
OTC or Prescription	Prescription use	Prescription use	Same

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
K number	**K261256**	**K121793**	/
Software/Firmware/ Microprocessor Control?	Yes	Yes	Same
Power Source	Polymer lithium battery (210mAh)	Battery type 675	Different **Note 1**
Design	Position transducers of the hearing aid over the temporal bones, close to ears and place the headband on the the back side of head.	Bone Conduction Aid which can be mounted with special Extension tips on different Eyeglasses.	Different **Note 2**
Target population	Adults and children (≥12 years)	Adults and children (≥12 years)	Same
Materials	ABS, PC, Silicone	Medical Grade plastics	Different, but solved by biocompatibility test
Operation mechanism	Circuit type: Digital Programmable:Yes Volume Control Channels: Two Volume control: Yes Mode switch: Yes Direct Audio Input: No Induction Coil: No Low Battery Indication: Yes Trimmer: Yes Program Switch Tones: Yes Output-Limitation: Yes	Circuit type: Digital Programmable:Yes Channels: Two Volume control: Yes Mode switch: Yes Direct Audio Input: No Induction Coil: Yes Low Battery Indication: Yes Trimmer: Yes Program Switch Tones: Yes Output-Limitation: Yes, MPO (Maximum Power Output)	Similar **Note 3**
Reporting of data	**According to IEC 60118-9:2019**	**According to DIN IEC 118-9:1987**	/
Maximum OFL90 (dB)	XTS-AISW-D1: 106 XTS-AISW-D2: 105 XTS-AISW-D3: 104	117dBOFL	Similar **Note 4**
High-frequency average OFL90 (dB)	XTS-AISW-D1: 101 XTS-AISW-D2: 99 XTS-AISW-D3: 97	113dBOFL	Similar **Note 4**
Maximum Full-on Gain (dB)	XTS-AISW-D1: 29.7 XTS-AISW-D2: 27.8 XTS-AISW-D3: 29.9	48dB	Different **Note 4**
Full-on Gain (High-Frequency Average) (dB)	XTS-AISW-D1: 26.5 XTS-AISW-D2: 25.0 XTS-AISW-D3: 23.5	Not publicly available	Different **Note 4**

Comparison Elements	**Subject Device**	**Predicate Device**	**Remark**
K number	**K261256**	**K121793**	/
Equivalent Input Noise Level (dB)	XTS-AISW-D1: 11 XTS-AISW-D2: 13 XTS-AISW-D3: 15	26dB	Different **Note 5**
Total Harmonic Distortion (THD)	XTS-AISW-D1: 1.5% XTS-AISW-D2: 1.5% XTS-AISW-D3: 1.5%	Not publicly available	Different **Note 6**

Comparison in Detail(s):

Note 1:

Though the power source is different from the predicate device, they are both powered by internal rechargeable battery. The lithium battery of the subject device complies with the IEC 62133-2 standard, and the device is complies with IEC 60601-1 and IEC 60601-1-2 requirements, so this difference will not raise any safety or effectiveness issues.

Note 2:

Though the design of the subject device is a little different from the predicate device, the use method and work principle of the subject device and the predicate device is the same, their transducer of the device is held against the head and is driven electrically by the amplifier to transmit the amplified sound as vibrations to the underneath bones of the skull, therefore, this difference will not raise any safety or effectiveness issues.

Note 3:

Though the subject device is not equipped with an induction coil, the device offers users with threes scenario modes (Mode 1: Noisy environment, Mode 2: Conventional environment, mode 3: Quiet environment) which can meet users' daily needs, and the device complies with IEC 60118-9 and IEC 60118-13 requirements, so this difference will not raise any safety or effectiveness issues.

Note 4:

Though the "Maximum OFL90", "High-frequency average OFL90", "Maximum Full-on Gain" and "Full-on Gain (High-Frequency Average)" are a slightly different from the predicate device, the subject device complies with the IEC 60118-9 standard and the parameters specification do not exceed the output tolerance range specified by the standard, which ensures that the device can precisely meet the hearing compensation needs of patients. Since the parameter settings depend on the degree of the user's hearing loss, the core of a hearing aid lies in precisely limiting the parameter output within a safe range to prevent any sound damage to the patient's remaining hearing. Therefore, such minor differences will not raise any safety or effectiveness issues.

Note 5:

Equivalent Input Noise Level reflects the noise level generated by the internal circuits of the hearing aid.

A lower equivalent input noise indicates that the device will not produce noticeable hissing sounds in a quiet environment, thereby providing a more comfortable listening experience. The equivalent input noise level of the subject device is smaller than that of the predicate device. Since a smaller equivalent input noise level means lower noise generated by the hearing aid, the performance of the subject device is superior to the predicate device, and the subject device also complies with the IEC 60118-9 requirements. Therefore, this difference will not cause any safety or effectiveness issues.

Note 6:

Lower total harmonic distortion indicates clearer and more accurate audio output, and the subject device complies with the IEC 60118-9 requirements, therefore, this difference will not cause any safety or effectiveness issues.

VII.Non-Clinical Testing

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

1) Electrical Safety

- IEC 60601-1: 2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC TS 60601-4-2: 2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- 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
- IEC 60118-13:2019 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices
- IEC 60118-9: 2019 Electroacoustics - Hearing aids - Part 9: Methods of measurement of the performance characteristics of bone conduction hearing aids
- IEC 62133-2: 2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

2) Biocompatibility Testing

- ISO 10993-5: 2009, Biological evaluation of medical devices – Par t 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

3) Software Verification and Validation

Software documentation consistent with ***Basic Documentation*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

- IEC 62304: 2015 Medical device software - Software life cycle processes

4) Cybersecurity & Wireless Coexistence

- UL ANSI 2900-1 First Edition 2017 Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements
- IEEE ANSI USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.

VIII. Clinical Testing

Not applicable.

IX. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.