June 15, 2026

Zdeer Technology (Henan) Co., Ltd.
Wenlin Xiang
Manager
East Of Wei Wu Rd. And S. Of Qin Gong E. Rd.,
Toubao Village Committee, Laotown Town
Changge, Xuchang City, Henan 461500
China

Re: K260452
Trade/Device Name: Bone Conduction Hearing Aid (G41157, G41158, G41159, G41160, G42151, G42152, G42153, G42154, G42155, G42156, G42157, G42158, G42159, G42160, G43151, G43152, G43153, G43154, G43155, G43156, G45151, G45152, G45153, G45154, G45155, G45156, G45157, G45158, G45159, G45160, G46151, G46152, G46153, G46154, G46155, G46156, G46157, G46158)
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 20, 2026
Received: May 20, 2026

Dear Wenlin Xiang:

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.	K260452

Please provide the device trade name(s).

Bone Conduction Hearing Aid (G41157, G41158, G41159, G41160, G42151, G42152, G42153, G42154, G42155, G42156, G42157, G42158, G42159, G42160, G43151, G43152, G43153, G43154, G43155, G43156, G45151, G45152, G45153, G45154, G45155, G45156, G45157, G45158, G45159, G45160, G46151, G46152, G46153, G46154, G46155, G46156, G46157, G46158)

Please provide your Indications for Use below.

The device is a wearable, non-invasive, and non-implanted bone conduction hearing aid intended to treat patients of patients aged 12 years and older with conductive hearing loss or single-sided deafness. It utilizes an ear-hook design to ensure stable mechanical coupling between the transducer and the temporal bone.

• Unilateral or bilateral conductive hearing loss, either chronic or temporary.

The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 25 dB HL.

• Single-sided deafness (i.e. unilateral profound sensorineural deafness) with normal hearing on the contralateral side. 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.

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) #: K260452

510(k) Summary

Prepared on: 2026-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zdeer Technology (Henan) Co., Ltd
Applicant Address	East of Wei Wu Road and south of Qin Gong East Road, Toubao Village Committee, Laotown Town Changge, Xuchang City Henan 461500 China
Applicant Contact Telephone	+86-15527272371
Applicant Contact	Mr. Wenlin Xiang
Applicant Contact Email	1132075798@qq.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Bone Conduction Hearing Aid (G41157, G41158, G41159, G41160, G42151, G42152, G42153, G42154, G42155, G42156, G42157, G42158, G42159, G42160, G43151, G43152, G43153, G43154, G43155, G43156, G45151, G45152, G45153, G45154, G45155, G45156, G45157, G45158, G45159, G45160, G46151, G46152, G46153, G46154, G46155, G46156, G46157, G46158)
Common Name	Bone-conduction hearing aid
Classification Name	Hearing Aid, Bone Conduction
Regulation Number	874.3302
Product Code(s)	LXB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K172460	Adhere system	LXB
K121793	bone conduction hearing aid	LXB

Device Description Summary

21 CFR 807.92(a)(4)

This Bone Conduction Hearing Aid is a head-worn device featuring flexible, bendable construction with instant rebound for a secure and comfortable fit. Integrated with an input transducer, a signal conditioning unit, an output transducer (bone vibrator), and a lithium battery, the device captures sound signals, processes and amplifies them, then transmits the audio to the temporal bone via its bone vibrator—where sound is further conducted to the inner ear. Designed for patients with conductive hearing loss or single-sided deafness, this hearing aid leverages bone conduction technology to deliver targeted vibrations to the temporal bone, enabling effective sound transmission to the inner ear for auditory perception.

The device is fitted with a mode button, which allows users to toggle between three preset modes: General Mode, Denoise Mode and Deep Denoise Mode.

There are 38 different models (G41157, G41158, etc.), but that they have the same intended use and internal electrical components, and they only differ in button location, casing material, and performance parameters.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is a wearable, non-invasive, and non-implanted bone conduction hearing aid intended to treat patients of patients aged 12

years and older with conductive hearing loss or single-sided deafness. It utilizes an ear-hook design to ensure stable mechanical coupling between the transducer and the temporal bone.
• Unilateral or bilateral conductive hearing loss, either chronic or temporary.
The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 25 dB HL.
• Single-sided deafness (i.e. unilateral profound sensorineural deafness) with normal hearing on the contralateral side. 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Subject Device is substantially equivalent to the Predicate Device in terms of intended use, clinical indications, and fundamental operating principle. Both devices provide non-invasive bone conduction acoustic compensation for patients with conductive hearing loss or SSD, utilizing identical clinical thresholds (BC≤25 dB HL).

Technological Comparison 21 CFR 807.92(a)(6)

The subject device maintains the same technological characteristics as the predicate and reference devices regarding the indicated degree of hearing loss, target population, circuit type, and user features such as volume control and low battery alerts. Since the subject device's OFL90 performance falls within the established performance envelope defined by the Predicate and Reference devices, the differences in maximum output are considered clinically insignificant. The subject device has comparable electroacoustic performance in terms of ASML50, Equivalent Input Noise (EIN), and Total Harmonic Distortion (THD) when compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

1)BIOCOMPATIBILITY TESTING
The zdeer Bone Conduction Hearing Aid is compliant with the standard of ISO 10993-5 and ISO 10993-10, ISO 10993-23. The tests were conducted in compliance with applicable requirements in the 21 CFR Part 58 regulations.
2)ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)
Electrical safety, EMC and EMI testing were conducted on the zdeer Bone Conduction Hearing Aid. The zdeer Bone Conduction Hearing Aid complies with the applicable sections of the following standards: IEC 60601-1:2005+A2:2020, IEC 60601-1-11:2015+A1:2020, IEC 60601-1-6:2010 +A1:2013+A2:2020, IEC 62366:2007 +A1:2014, IEC 60601-1-2:2014 +A1:2020 and IEC TS 60601-4-2 :2024.
3)MECHANICAL AND OTHER TESTING
Bench testing was successfully performed in respect to the defined technical requirements such as:Appearance and Structure, Output force level for input sound pressure level of 90 dB （OFL90）, Acousto-mechanical Sensitivity Level (AMSL) at Reference Frequency, Equivalent Input Noise(EIN), Total Harmonic Distortion(THD), Frequency Response Range,Rated Power Supply Current Consumption, Manual Program Selection, Automatic Denoise Function, Number of Channels, Bluetooth Communication Function, Electrical Safety Requirements.
4)SOFTWARE VERIFICATION AND VALIDATION TESTING
Software verification and validation testing were conducted and basic level of documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions(2023)".
5)CYBERSECURITY
The Cybersecurity verification and validation was provided in accordance with the Guidance: Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions.

The non-clinical data provided support the safety of the device and the hardware verification and validation demonstrate that the zdeer Bone Conduction Hearing Aid should perform as intended in the specified use conditions. The performance data has confirmed that the product is substantially equivalent as the predicate device.