July 22, 2026

Sounduct
Camille Bonnassieux
Quality and Regulatory Manager
2, Rue Marie Hamm
Strasbourg, 67000
France

Re: K254296
Trade/Device Name: Ossiclear (Ossiclear System)
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: December 31, 2025
Received: December 31, 2025

Dear Camille Bonnassieux:

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,

JOYCE C. LIN -S

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254296

Device Name
Ossiclear (Ossiclear System)

Indications for Use *(Describe)*
Ossiclear System is indicated for the following patients aged 12 years and older:

• 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 3 kHz) should be better than or equal to 55 dB HL.

• Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally moderate to profound conductive or mixed hearing loss. Symmetrical bone conduction thresholds are defined as less than a 10 dB HL average difference between ears (measured at 0.5 1 2 and 3 kHz), or less than a 15 dB HL 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 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.

• Any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

A. Submitter information

Submitted by: SOUNDUCT
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6700 Strasbourg – FRANCE

Contact: Camille BONNASSIEUX
Quality and Regulatory Affairs Manager
SOUNDUCT
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B. Date Prepared

July 22nd, 2026

C. Device Name and Classification

Device Name:	Ossiclear System
Device Trade Name:	Ossiclear
Classification Name:	Hearing aid, bone conduction - 21 CFR 874.3302, Class II
Classification Panel	Ear Nose & Throat
Device Product Code:	LXB

D. Predicate and Reference devices

Predicate device Trade Name:	Cochlear™ Baha® System, Cochlear™ Baha® Fitting Software 6, Cochlear™ Baha® Baha Smart App
Classification Name:	Hearing Aid, Bone Conduction - 21 CFR 874.3302, Class II
Classification Panel	Ear Nose & Throat
510(k) Number:	K212136
Product Code:	LXB

ADHEAR System

Reference device Trade Name:

Classification Name:	Hearing Aid, Bone Conduction - 21 CFR 874.3302, Class
Classification Panel	II Ear Nose & Throat
510(k) Number:	K172460
Product Code:	LXB

E. Device Description

The Ossiclear System is a non-invasive bone conduction hearing aid intended to improve hearing by transmitting sound vibrations through bone to the cochlea. The system includes the Ossiclear Bone Hearing Device (BHD), which contains microphones, signal processing technology, and a rechargeable battery. The BHD is secured to the skin using single-use adhesive (Ossiclear Stick Pads) specifically designed for compatibility with the Ossiclear System.
The Ossiclear DOCK is a portable charging station and storage case for one BHD, allowing safe and convenient charging. The Ossiclear Pro Fitting Suite is a professional software application intended for qualified hearing care professionals to configure, program, and fit the Ossiclear BHD according to each patient's audiometric profile. The Ossiclear SmartApp is an optional mobile application that enables patients to monitor and control their device.

Together, these components work as one system for patients with conductive or mixed hearing loss or single-sided deafness.

F. Intended / Indication for use statement

The Ossiclear system is a non- invasive two-point bone conduction hearing aid solution. The Ossiclear system, attaches to the skin via Ossiclear Stick Pads, uses bone conduction to transmit sounds to the cochlea (inner ear) with the purpose of enhancing hearing. Ossiclear Pro Fitting Suite is a fitting software used to program Ossiclear BHD and modify hearing profiles to provide comfortable and usable gain for recipients. Ossiclear SmartApp is a mobile application that provides digital support for patients in controlling and monitoring the Ossiclear BHD.

Ossiclear System is indicated for the following patients aged 12 years and older:

- 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 3 kHz) should be better than or equal to 55 dB HL.

- Bilateral fitting is intended for patients who meet the above criterion in both ears, with bilaterally moderate to profound conductive or mixed hearing loss. Symmetrical bone conduction thresholds are defined as less than a 10 dB HL average difference between ears (measured at 0.5 1 2 and 3 kHz), or less than a 15 dB HL 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 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.
- Any patient who is indicated for an air conduction contralateral routing of signals (AC CROS) hearing aid.

G. Device Comparison Table (Subject vs. Predicate vs. Reference)

Characteristic	Subject Device (Ossiclear)	Predicate Device (Cochlear BAHA 6 System)	Reference Device (ADHEAR System)	Comments/Equivalence
Regulatory Name	Ossiclear	Cochlear BAHA 6 System	ADHEAR System	Same intended category
510(k) #	K254296	K212136	K172460	Reference supports adhesive fixation
Product Code	LXB	LXB	LXB	Same
Class	II	II	II	Same
Regulation Number	874.3302	874.3302	874.3302	Same
Intended Use	Non-invasive bone conduction hearing aid using adhesive pads; includes Pro Fitting Suite & SmartApp	Bone conduction hearing aid; includes Baha Fitting Software & Smart App	Non-invasive bone conduction hearing aid using adhesive adapter or headband	Same principle; adhesive fixation supported by reference device
Indications for Use	Conductive/mixed HL ≤55 dB HL; SSD; AC-CROS	Conductive/mixed HL ≤55 dB HL; SSD; AC-CROS	Conductive HL ≤25 dB HL; SSD	Aligned with predicate; reference covers adhesive use
Target Population Age	≥12 years	All ages	All ages	The subject device's target population is covered by the predicate device, and the same indications for use
Surgical Requirement	Non-surgical (adhesive)	Surgical for implant; non-surgical options available	Non-surgical (adhesive)	Subject offers only non-surgical option; supported by reference
Prescription Use	Rx Only	Rx Only	Rx Only	Same
System Components	External sound processor + adhesives + portable charging station	External sound processor + softband/SoundArc or implant coupling	External sound processor + adhesives	Similar; adhesive solution validated

Processor Components	Dual microphones; LED; Battery; Two Axisymmetric electromagnetic transducer; Independent adhesives	Dual microphones; LED; Battery; On device button to change programs; Symmetrical electromagnetic transducer	Single microphone; LED; battery; On device button to change programs; unique vibration system; Independent adhesives	Subject device is equivalent to predicate device except for including 2 axisymmetric electromagnetic transducers & independent adhesives (supported by the reference device). Electroacoustic bench testing per IEC 60118-9:2019 demonstrates comparable output performance. Independent adhesive fixation was validated through peel adhesion strength testing per ASTM D3330. These results confirm that the differences in transducer configuration and fixation method do not raise new questions of safety or effectiveness.
Battery Type	1454 Li-ion rechargeable	312 zinc-air	13 zinc-air	Different type; safety addressed via IEC 60601-1
Materials	Biocompatible	Biocompatible	Biocompatible	Same
Adhesive Lifetime	1 day	N/A	3–7 days	Comparable to reference; ISO 10993 compliance
Principle of Operation	Bone conduction	Bone conduction	Bone conduction	Same
Software	Configurable; Pro Fitting Suite & SmartApp	Configurable; Baha Fitting Software & Smart App	Configurable	V&V testing demonstrated that the Pro Fitting Suite and SmartApp perform their intended functions, including device programming, hearing profile management, device control, and user interaction. Testing confirmed that software differences compared to the predicate device do not affect intended use, performance, safety, or effectiveness and do not raise new questions of substantial equivalence.

Core similarities in principle, intended use, and essential functionality outweigh implementation differences (fixation via single-use adhesives, rechargeable battery, dual-transducer architecture, software with fewer setting tools). These differences do not affect intended use or raise new questions of safety or effectiveness, as confirmed by verification and validation testing.

H. Summary of Performance Testing

Testing used production-equivalent devices under approved V&V plans with predefined acceptance criteria.

a. *Biocompatibility*

The Ossiclear System was evaluated for biological safety in accordance with ISO 10993 and FDA guidance. Biocompatibility testing was performed on representative samples for cytotoxicity, sensitization, and irritation, and all results met acceptance criteria, confirming that the device is biocompatible for its intended use.

b. *Electrical & Thermal Safety / Home-use Usability*

The Ossiclear System (BHD and Dock) was evaluated for electrical and thermal safety in accordance with IEC 60601-1, IEC 60601-1-6, and IEC 60601-1-11, and usability was validated per IEC 62366-1. Testing confirmed compliance with applicable safety requirements, and usability validation demonstrated that critical tasks were completed successfully without hazardous use errors. These results confirm that the Ossiclear System is safe for home use and presents no unacceptable residual risks.

c. *Electromagnetic Compatibility (EMC)*

The Ossiclear System was evaluated for electromagnetic compatibility in accordance with IEC 60601-1-2 and applicable FCC requirements. The evaluation included emissions and immunity tests using the methods and acceptance criteria defined by the standards.

All tests were successfully passed, with no degradation of safety or essential performance observed during or after exposure to electromagnetic disturbances. The device meets all relevant international and U.S. requirements for EMC, and Bluetooth radio emissions comply with FCC Part 15 limits, with no unintended emissions outside approved frequency bands.

d. Bench Testing

The Ossiclear System underwent non-clinical bench testing to verify compliance with design specifications and demonstrate substantial equivalence to the predicate device. Testing included evaluation of key electroacoustic performance characteristics of the Ossiclear BHD, such as output, gain, frequency response, noise, and distortion, using recognized bench test methods for bone conduction hearing devices.

All tests met predefined acceptance criteria. These results confirm that the Ossiclear System performs as intended and supports its substantial equivalence.

e. Software & Cybersecurity (Pro Fitting Suite & SmartApp)

The Ossiclear System includes embedded software within the BHD and DOCK, as well as two external applications: Pro Fitting Suite (for professional fitting) and SmartApp (optional patient mobile app). All software was developed in compliance with IEC 62304, classified as Class A, and assessed as Level of Concern: Minor. Verification confirmed that all software components meet functional and performance requirements and operate as intended.

Cybersecurity was addressed following FDA guidance *'Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions'*. The Ossiclear SmartApp was developed under a secure-by-design, monitored-for-life approach, incorporating secure coding, authentication and encrypted communication, controlled update processes, and continuous vulnerability monitoring. All activities confirmed that residual cybersecurity risk is acceptable and that the software supports safe and effective operation of the Ossiclear System.

f. Labeling & UDI / Instruction For Use

The Ossiclear System labeling was developed in compliance with FDA and applicable international requirements. Product and packaging labels include the Unique Device Identifier (UDI) in accordance with regulatory requirements, ensuring traceability and correct identification.

The Instructions for Use (IFU) were validated through usability testing per IEC 62366-1 and include comprehensive guidance for device setup, removal, charging procedures, routine care, and safe disposal. The IFU also addresses troubleshooting, maintenance, and safety information to support proper and safe use in home and clinical environments.

g. Clinical Data

No clinical data required for substantial equivalence; non-clinical performance and technological comparability are sufficient.

I. Conclusion

Based on the indications for use, technological characteristics, comparison to the predicate device, and performance data, the Ossiclear System has been demonstrated to be as safe and effective as the predicate device for its intended use. The differences in design, including the use of consumable adhesive pads for fixation, do not raise new questions of safety or effectiveness and have been addressed through verification and validation testing. Therefore, the Ossiclear System is substantially equivalent to the predicate device, Cochlear™ Baha® 6 System (K212136), with supporting evidence from the reference device ADHEAR System (K172460).