April 25, 2025

BHM-Tech Produktionsgesellschaft mbH
Markus Hirtzi
Quality Control, Regulatory Affairs
Grafenschachen 242
Grafenschachen, 7423
Austria

Re: K243041
Trade/Device Name: contact forte Alpha
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: March 28, 2025
Received: March 28, 2025

Dear Markus Hirtzi:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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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.

Submission Number *(if known)*

K243041

Device Name

contact forte Alpha

Indications for Use *(Describe)*

The contact forte Alpha is a Processor and is intended for use with the Sophono Headband or Softband (no age limitations), or with the Sophono Magnetic Implant (patients 5 years of age and up) for the following patients and indications:
• Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1,2, and 3 kHz).
• Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an Air Conduction Contralateral Routing of Signal (AC CROS). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5,1, 2 and 3 kHz).

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.

510(k) #: K243041

510(k) Summary

Prepared on: 2025-04-25

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BHM-Tech Produktionsgesellschaft mbH
Applicant Address	Grafenschachen 242 Grafenschachen 7423 Austria
Applicant Contact Telephone	+43 3359 200 78
Applicant Contact	Mr. Markus Hirtzi
Applicant Contact Email	mhirtzi@bhm-tech.at

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	contact forte Alpha
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
K153391	Sophono Bone Conduction Systems (S) Configuration and (M) C	LXB

Device Description Summary

21 CFR 807.92(a)(4)

The contact forte Alpha Processor is a sound processor that converts sound into mechanical vibrations. The sound processor is magnetically connected to a Sophono Headband, Sophono Softband or Sophono Attract Magnetic Spacer by the integrated metal disk. Sound enters the audio processor through the microphones, which then goes through a DSP chip for signal processing. The output of the DSP chip drives an electromechanical transducer, which converts the signal into mechanical vibrations. These vibrations are transferred to the patient's skin through either the Sophono Headband, Sophono Softband or the Sophono Attract magnetic spacer. The vibrations are carried through the patient's skin and skull to the cochlea where they are perceived as sound. The device is designed for use on either the right or left side application. The device has a "oval" housing with a symmetrical design (for right or left side application). The material used: Plastic - contact with intact skin;

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The contact forte Alpha is a Processor and is intended for use with the Sophono Headband or Softband (no age limitations), or with the Sophono Magnetic Implant (patients 5 years of age and up)
for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1,2, and 3 kHz).
- Bilateral fitting is applicable for most patients having a symmetrically conductive or mixed hearing loss. The difference between the left and right sides' BC thresholds should be less than 10 dB on average measured at 0.5, 1, 2, and 4 kHz, or less than 15 dB at individual frequencies.
- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an Air Conduction Contralateral Routing of Signal (AC CROS). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5,1, 2 and 3 kHz).

Indications for Use Comparison

21 CFR 807.92(a)(5)

Same intended use. Both - Sophono (Medtronic) and contact forte Alpha (BHM) - are sound processors that convert sound into mechanical vibrations. The vibrations are carried through the patient's skin and skull to the cochlea where they are perceived as sound.

The contact forte Alpha is developed and manufactured by BHM-Tech Produktionsgesellschaft mbH in Austria. The contact forte Alpha is only a Sound processor and is intended to be used with Sophono Bone Conduction Systems from METRONIC XOMED, INC.
This combination reflects the same application possibility as with the Sophono Alpha 2 sound processor, which was initially part of the overall MEDTRONIC-Sophono Bone Conduction System.
Note that the MEDTRONIC system is discontinued and no new sound processors are produced. The combination with the BHM processor allows patient to upgrade to a new sound processor and/or replace their defective processor without having to change the implant.

Technological Comparison

21 CFR 807.92(a)(6)

Same technological characteristics:
- converting sound into mechanical vibrations
- battery type: 13 (PR 48, Zinc-Air)
- max. output: 114 dBOFL
- full on gain (max): 51dB
- programmable
- frequency processing: 16 band, 8 channels
- number of programs: 4
- individual patient fitting via fitting software
- housing - material: plastic (ABS, PA)
- contact with intact skin only (short term only, e.g. cleaning)
- no direct skin contact when used as intended

1.
Intended Use & Indications for Use
Both the contact forte Alpha Sound Processor and the Sophono Alpha 2 Sound Processor are bone conduction hearing devices intended to amplify sound for individuals with conductive, mixed, or single-sided deafness. They are designed to be used with an implantable or non-implantable bone conduction system to enhance auditory perception. There is no significant difference in their intended use, supporting substantial equivalence.
2.
Technological Characteristics
Bone Conduction Technology: Both devices use direct bone conduction to transmit sound vibrations to the inner ear.
Sound Processing: The digital signal processing (DSP) in both devices provide sound amplification and frequency adjustments based on patient needs.
Attachment Mechanism: Both models are designed to attach magnetically to an implanted or non-implanted-based coupling system.
Power Source: Both devices are powered by standard zinc-air batteries (Sophono Alpha2 may also be powered by rechargeable batteries), ensuring similar operational performance.
Materials & Biocompatibility: The external casing and skin-contacting materials are biocompatible and conform to ISO 10993 standards.
3.
Performance Data & Safety Considerations
Acoustic Performance: Comparative testing has shown that both devices deliver identical gain, output, and speech intelligibility performance .
Electromagnetic Compatibility (EMC): Both processors comply with IEC 60601-1-2 for EMC requirements.
Safety & Effectiveness: No new safety concerns are introduced, and risk assessment (per ISO 14971) confirms that the risk profile remains equivalent between the two devices.
Field testing was conducted with five patients to assess whether the subject device performed as intended under real-world conditions. Results showed that performance with the contact forte Alpha was comparable to that of the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Magnetic Retention forces in different clinically significant configurations as well as Output Level Measurements with contact forte Alpha and Sophono Alpha 2 was done.
Good concordance was seen between device outputs across the various clinically relevant configurations. Measurements have shown that there is no difference between the devices which affects the safety and performance of the devices. The acceptance criteria for all defined tests were met.

Field tests: The field measurements showed that Sophono Alpha2 as well as contact forte Alpha are delivering comparable gain and output levels. A head to head comparison of the subject and predicate device showed that audiometric thresholds and speech

perception thresholds for the two devices were not measurably different for five different users. The patients reported that they did not notice any subjective difference in hearing between the two devices.

Based on the results of nonclinical and clinical testing, the contact forte Alpha has been demonstrated to be as safe, as effective, and to perform as well as the legally marketed predicate device, the Sophono Alpha 2. The nonclinical tests, including biocompatibility, mechanical performance, and electromagnetic compatibility demonstrate compliance with applicable safety standards.

These findings provide reasonable assurance that the contact forte alpha is substantial equivalent to the predicate device.