July 29, 2020

MED-EL Elektromedizinische Geraete GmbH
Carolin Ralser
Advanced Regulatory Affairs Specialist
Fuerstenweg 77a
Innsbruck, Tirol 6020
Austria

Re: K200504
Trade/Device Name: BONEBRIDGE System, SAMBA 2 BB, SYMFIT 8.0, SAMBA 2 GO, SAMBA 2 Remote
Regulation Number: 21 CFR 874.3340
Regulation Name: Active implantable bone conduction hearing system
Regulatory Class: Class II
Product Code: PFO
Dated: June 29, 2020
Received: July 2, 2020

Dear Carolin Ralser:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Michael J. Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200504

Device Name
BONEBRIDGE or Bonebridge

Indications for Use *(Describe)*

INTENDED USE:
The Bonebridge is intended to improve hearing for patients with conductive or mixed hearing losses, bilateral fitting, and single-sided deafness.

INDICATIONS:
The Bonebridge bone conduction hearing implant system is intended for the following patients and indications:
- Patients 12 years of age or older.
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the Bonebridge is intended for 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 3kHz, or less than 15 dB at individual frequencies.
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at 0.5, 1, 2 and 3kHz).
- The Bonebridge 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.
- Prior to receiving the device, it is recommended that an individual has experience with appropriately fit air conduction or bone conduction hearing aids.

CONTRAINDICATIONS:
- Chronic or non-revisable vestibular or balance disorders.
- Abnormally progressive hearing loss.
- Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment.
- Skin or scalp conditions that may preclude attachment of the audio processor or that may interfere with the use of the audio processor.
- Skull size or abnormality that would preclude appropriate placement of the Bonebridge implant as determined by CT scan.

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.

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510(k) Summary

Applicant:
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Date prepared: July 28, 2020

1. Device Information

Trade Name:

SAMBA 2 BB

SYMFIT 8.0

SAMBA 2 GO

SAMBA 2 Remote

Generic/Common Name:

Active Implantable Bone Conduction Hearing System

Classification

Class II active implantable bone conduction hearing system, per 21 CFR 874. 3340

Classification Panel:

Ear, Nose, and Throat

Product Code:

PFO

2. Predicate Devices

Samba BB, SYMFIT 7.0 and Remote Control - MED-EL Elektromedizinische Geraete GmbH (K183373)

3. Device Description

The MED-EL BONEBRIDGE System augments hearing by providing acoustic input to the inner ear via bone conduction.

The SAMBA 2 BB is an external audio processor of the existing MED-EL BONEBRIDGE System. The MED-EL BONEBRIDGE System consists of two major components: The implant, called Bone Conduction Implant (BCI) and the external audio processor, e.g. the SAMBA 2 BB. The SYMFIT 8.0 software enables the fitting and configuration of the SAMBA 2 BB audio processor and is indicated for professional use only, i.e. used by hearing healthcare professionals during a fitting session of the external audio processor SAMBA 2 BB.

Additionally, the SAMBA 2 GO and SAMBA 2 Remote are also subject to this 510(k). Both devices offer a convenient option to adjust simple, pre-defined settings of the compatible SAMBA 2 BB audio processor. Additionally, the SAMBA 2 GO can also be used as an assistive streaming device.

The SAMBA 2 BB external audio processor is the successor device of the predicate Samba BB external audio processor (K183373) with the identical intended use, indications and contraindications.

The SYMFIT 8.0 software is the successor device of the predicate SYMFIT 7.0 software (K183373) with the identical intended use, indications and contraindications.

The SAMBA 2 GO and SAMBA 2 Remote are successor devices of the predicate Remote Control (K183373) with the identical intended use, indications and contraindications.

4. Indications for Use

The BONEBRIDGE bone conduction hearing implant system is intended for the following patients and indications:

- Patients 12 years of age or older.
- Patients who have a conductive or mixed hearing loss and still can benefit from sound amplification. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5,1, 2, and 3 kHz) should be better than or equal to 45 dB HL.
- Bilateral fitting of the BONEBRIDGE is intended for 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 3 kHz, or less than15 dB at individual frequencies.
- Patients who have profound sensorineural hearing loss in one ear and normal hearing in the opposite ear (i.e., single-sided deafness or "SSD"). The pure tone average air conduction hearing thresholds of the hearing ear should be better than or equal to 20 dB HL (measured at0.5, 1, 2, and 3 kHz).
- The BONEBRIDGE for SSD is also indicated for any patient who is indicated for an airconduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

- Prior to receiving the device, it is recommended that an individual have experience with appropriately fit air conduction or bone conduction hearing aids.

5. Contraindications

- Chronic or non-revisable vestibular or balance disorders.
- Abnormally progressive hearing loss.
- Evidence of conditions that would prevent good speech recognition potential as determined by good clinical judgment.
- Skin or scalp conditions that may preclude attachment of the audio processor or that may interfere with the use of the audio processor.
- Skull size or abnormality that would preclude appropriate placement of the Bonebridge implant as determined by CT scan.

6. Technological Characteristics

The MED-EL BONEBRIDGE System is an active implantable bone conduction hearing system. The MED-EL BONEBRIDGE System is a prescription device consisting of an implanted transducer, implanted electronics components, and an audio processor. The active implantable bone conduction hearing system is intended to compensate for conductive or mixed hearing losses by conveying amplified acoustic signals to the cochlea via mechanical vibrations on the skull bone. The updates to the MED-EL BONEBRIDGE System do not affect the device intended use, fundamental operating principles or functional characteristics.

Predicate Comparison and Discussion

The SAMBA 2 BB, SYMFIT 8.0, SAMBA 2 GO and SAMBA 2 Remote have the same intended use, indications and contraindications as their predicate devices Samba BB, SYMFIT 7.0 and Remote Control.

The SAMBA 2 BB audio processor is a further development with the currently marketed predicate device Samba BB audio processor and compatible with the existing MED-EL BONEBRIDGE System. The primary modifications proposed are to the size and shape of the device as well as the provision of improved optional signal processing and connectivity features. The SYMFIT 8.0 fitting software is a further development of the currently marketed predicate device SYMFIT 7.0 and has been updated to support fitting of the SAMBA 2 BB audio processor. The SAMBA 2 GO and SAMBA 2 Remote are further developments of the currently marketed predicate device Remote Control. The primary modification of the SAMBA 2 GO is the provision of additional streaming functionality whereas the primary modification of the SAMBA 2 Remote is to provide an alternative option to remotely control compatible audio processors via a mobile application.

Table 1: Comparison of Technological Characteristics SAMBA 2 BB with predicate K183373

Characteristics / Features	Comparison and Discussion – SAMBA 2 BB with predicate device K183373
Design Concept	The predicate device and the SAMBA 2 BB audio processor share the same basic design concept and technological characteristics, i.e. all components are integrated into a single-unit housing using the same electronics and housing material and similar stimulation strategies. The main differences in design characteristics of SAMBA 2 BB compared with the predicate device are as follows: - The SAMBA 2 BB uses a revolving battery door whereas the predicate uses a sliding battery door. - The SAMBA 2 BB has slightly different dimensions and is lighter than the predicate. - The SAMBA 2 BB offers an additional magnet strength option. - The microphone protection membrane used for the SAMBA 2 BB is mounted on the exchangeable outer cover whereas for its predicate device the same microphone protection membrane is mounted onto the housing. - The SAMBA 2 BB uses two omnidirectional microphones like its predicate device. SAMBA 2 BB uses a different type of microphones (MEMS). - The SAMBA 2 BB has a higher ingress protection (IP) rating The overall design concept of the SAMBA 2 BB compared with its predicate device remains unchanged. Bench testing has been conducted to confirm that the differences in design characteristics do not affect safety or effectiveness of the SAMBA 2 BB.
Energy source	The SAMBA 2 BB uses the same energy source as its predicate device.
Materials in skin contact	Main materials in skin contact used for SAMBA 2 BB have been evaluated according to 10993-1 and shown to be biocompatible and safe for human use. The main housing material used in SAMBA 2 BB is identical with the main housing material used in its predicate device.
Signal Processing	The signal processing of SAMBA 2 BB features the same basic functionality as the signal processing used with its predicate device; additionally, SAMBA 2 BB allows for new optional noise reduction features, new optional compression settings as well as improved acoustic classification. The overall performance of SAMBA 2 BB remains identical when compared with its predicate. Bench testing has been conducted to confirm that the differences

Characteristics / Features	Comparison and Discussion – SAMBA 2 BB with predicate device K183373
	in signal processing do not affect safety or effectiveness of the SAMBA 2 BB.
Connectivity	The SAMBA 2 BB offers identical connectivity options as its predicate device. Additionally, SAMBA 2 BB supports an acoustic interface to receive commands from compatible MED-EL Wireless Accessories. Bench testing has been conducted to confirm that the differences in connectivity options do not affect safety or effectiveness of the SAMBA 2 BB.

Table 2: Comparison of Technological Characteristics SYMFIT 8.0 with predicate K183373

Characteristics / Features	Comparison and Discussion –SYMFIT 8.0 with predicate device K183373
Design Concept	SYMFIT 8.0 is needed to program the SAMBA 2 BB audio processor. The basic working principle as well as the operational environment of SYMFIT 8.0 remains identical when compared with its predicate device. SYMFIT 8.0 has the same moderate level of concern as its predicate device and is used for the same purpose. The Software architecture of SYMFIT 8.0 has been improved. The workflow of SYMFIT 8.0 is identical with the workflow of its predicate device but better graphically represented by a user interface adapted to the existing BONEBRIDGE fitting process. The overall design concept of SYMFIT 8.0 remains identical when compared with its predicate. Bench and usability testing have been conducted to confirm that the differences in design do not affect safety or effectiveness of the SYMFIT 8.0.
Fitting Features	The fitting features of SYMFIT 8.0 provide the same basic functionality as the fitting features used with its predicate device; additionally, SYMFIT 8.0 allows for new optional fine-tuning features with regards to compression settings. The overall performance of SYMFIT 8.0 remains identical when compared with its predicate. Bench testing has been conducted to confirm that the differences in the fitting features do not affect safety or effectiveness of the SYMFIT 8.0.

Table 3: Comparison of Technological Characteristics SAMBA 2 GO and SAMBA 2 Remote with predicate K183373

Characteristics / Features	Comparison and Discussion –SAMBA 2 GO and SAMBA 2 Remote with predicate device K183373
Design Concept	The SAMBA 2 GO is an external hardware device. Its overall design concept has been slightly updated compared with its predicate device as the SAMBA 2 GO comes in form of a neckloop, which also works as an antenna. The SAMBA 2 Remote is a mobile application operated on either an Android or iOS platform. The app-specific design of the SAMBA 2 Remote has no impact on the safety or effectiveness of the medical functionality of the SAMBA 2 Remote, i.e. remote-control features. Bench testing has been conducted to confirm that the differences in design do not affect safety or effectiveness of the SAMBA 2 GO and SAMBA 2 Remote.
Remote Control Features	SAMBA 2 GO and SAMBA 2 Remote provide identical remote-control features as their predicate device. SAMBA 2 Remote provides the additional optional Sound Balancing feature. This feature gives additional comfort to the user in certain environments. Bench testing has been conducted to confirm that the differences in remote-control features do not affect safety or effectiveness of the SAMBA 2 GO and SAMBA 2 Remote.
Connectivity	SAMBA 2 GO uses the identical wireless connection as its predicate. The SAMBA 2 GO enables streaming functionality and can thus be paired with Bluetooth-enabled devices or line-in devices. This function has no medical purpose and no impact on safety and effectiveness. The SAMBA 2 Remote uses an acoustic interface to connect wirelessly with the SAMBA 2 BB audio processor. Bench testing has been conducted to confirm that the differences in connectivity do not affect safety or effectiveness of the SAMBA 2 GO and SAMBA 2 Remote.

7. Performance Data

All necessary bench testing was conducted on SAMBA 2 BB, SYMFIT 8.0, SAMBA 2 GO and SAMBA 2 Remote to support determination of substantial equivalence to the existing BONEBRIDGE. The non-clinical bench tests included:

- Testing on electrical and performance characteristics
- Compatibility Testing
- Reliability Testing

- Shipping Test
- Environmental Testing (solar radiation, substance resistance, resistance against light of certain wavelength)
- Electrical Safety Testing
- Electromagnetic compatibility testing
- Software testing according to software's defined Level of Concern

The results of the non-clinical performance testing demonstrate that SAMBA 2 BB, SYMFIT 8.0, SAMBA 2 GO and SAMBA 2 Remote meets the established specifications to ensure consistent and safe performance for its intended use.

8. Conclusion

The safety and effectiveness testing performed for the devices show that the SAMBA 2 BB, SYMFIT 8.0, SAMBA 2 GO and SAMBA 2 Remote perform as intended and confirm that they are at least as safe and effective as the predicate devices.

The SAMBA 2 BB, SYMFIT 8.0, SAMBA 2 GO and SAMBA 2 Remote are substantially equivalent to the predicate devices.