



March 7, 2019

MED-EL Elektromedizinische Geraete GmbH
Stephanie Haselwanter
Team Leader, Global Registrations
Fuerstenweg 77a
Innsbruck, 6020 At

Re: K183373

Trade/Device Name: Bonebridge
Regulation Number: 21 CFR 874.3340
Regulation Name: Active implantable bone conduction hearing system
Regulatory Class: Class II
Product Code: PFO
Dated: November 29, 2018
Received: December 6, 2018

Dear Stephanie Haselwanter:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K183373

Device Name

BONEBRIDGE

Indications for Use (Describe)

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 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 3 kHz).
- 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 have experience with appropriately fit air conduction or bone conduction hearing aids.

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 – K183373

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92

510(k) SUMMARY

I. Submitter

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II. Date Prepared

November 29th, 2018

III. Device

Trade Name:

BONEBRIDGE

Generic/Common Name:

Active Implantable Bone Conduction Hearing System

Classification:

Class II, 21 CFR§874.3340

Classification Panel:

Ear, Nose, and Throat

Product Code:

PFO

IV. Predicate Devices

BONEBRIDGE (DEN170009)

V. Purpose of Submission

The purpose of this premarket notification is to update the BONEBRIDGE product labelling for EMC and MRI to remove specific EMC cautionary information and to label the BCI 601 implant as MR conditional at 1.5T. The intended use of the modified device, as described in the labelling, has not changed as a result of the modification(s).

No changes have been made to the devices themselves. Only the product labelling is affected.

VI. Device Description

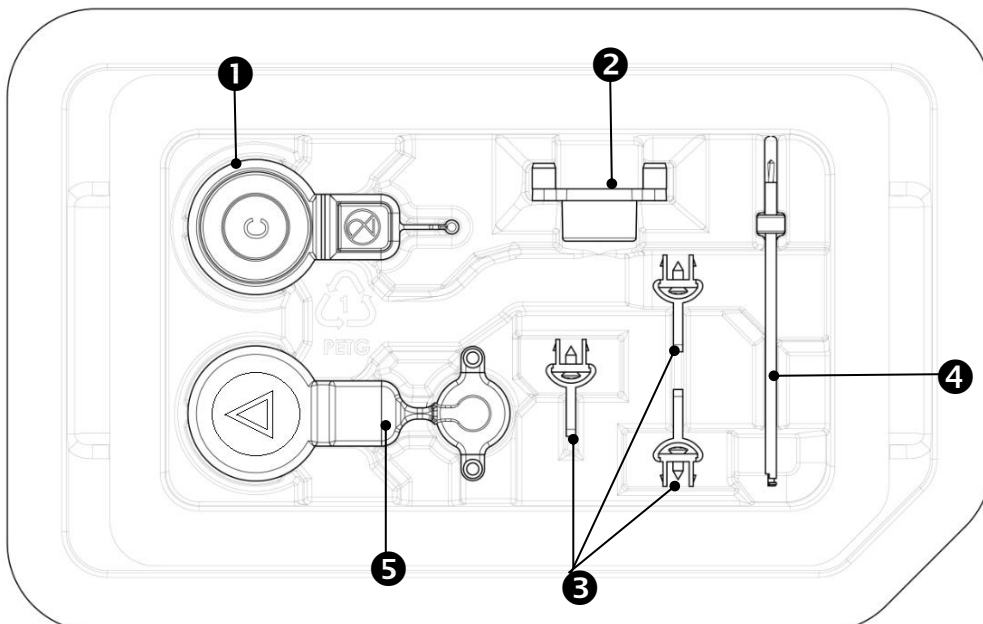
BONEBRIDGE augments hearing by providing acoustic input to the inner ear via bone conduction. BONEBRIDGE consists of the following components: The Bone Conduction Implant (BCI) and the externally worn audio processor.

The BCI 601 implant is provided in an implant kit together with two templates to determine optimal implant placement, one drill bit, two regular cortical titanium screws (gold surface) and one emergency screw (blue surface).

All devices are shipped in one sterile tray and are for single-use only.

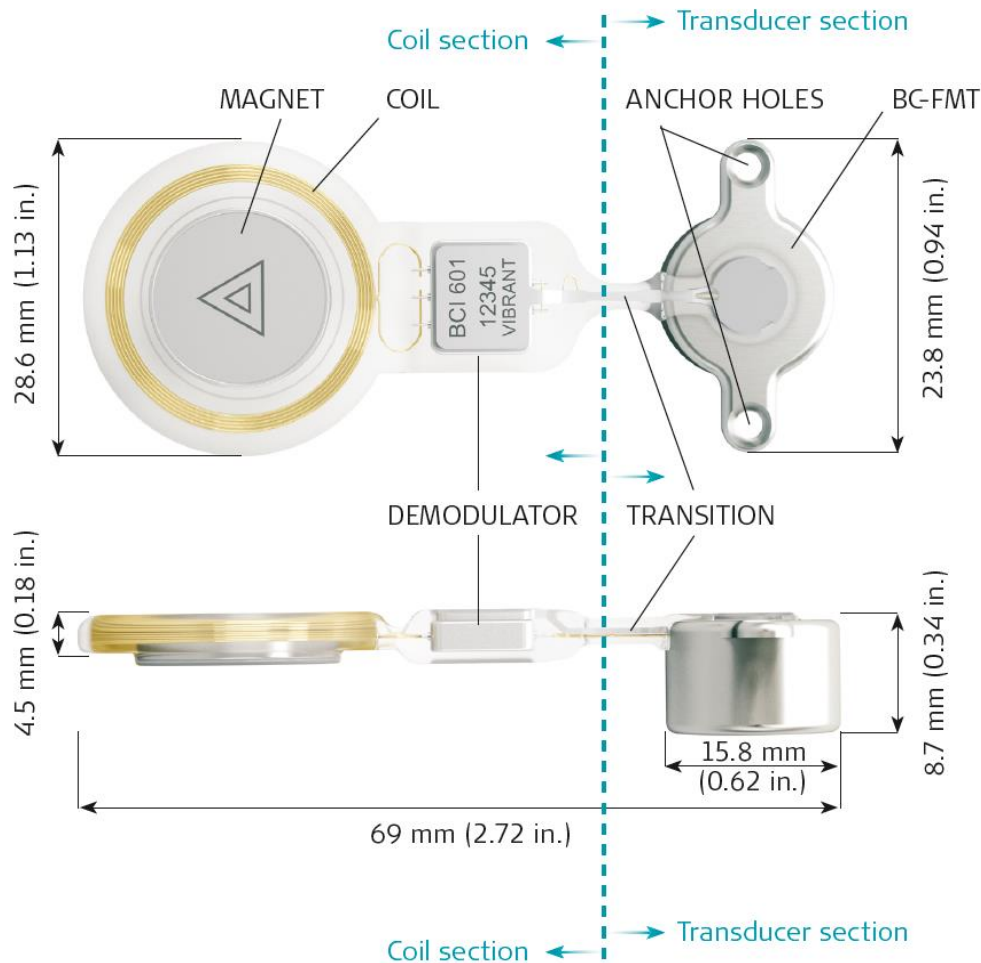
Contents of the BCI 601 Implant Kit

- ❶ Coil-Sizer (template representing coil section, see Figure 2, called "C-Sizer")
- ❷ Transducer-Sizer (template representing transducer section, see Figure 2, called "T-Sizer")
- ❸ Cortical titanium screws [2 regular screws (gold surface), 1 emergency screw (blue surface)]
- ❹ Drill bit with stopper (requires handpiece with dental coupling)
- ❺ Bone Conduction Implant (BCI 601)



The Bone Conduction Implant (BCI) is the implantable part of BONEBRIDGE and can only be used together with compatible MED-EL external components. The device is an osseointegrated bone conduction implant system, intended to provide a level of useful sound perception for individuals with conductive and mixed hearing loss, as well as those suffering from single-sided deafness. The BCI is surgically implanted into the mastoid bone.

The BCI 601 has two main sections, the coil section and the transducer section.



The BCI 601 consists of a magnet surrounded by the receiver coil, the electronics (demodulator), the transition and the Bone Conduction – Floating Mass Transducer (BC-FMT). The BCI 601 is activated by placing the external audio processor over the magnet of the BCI 601. The signal and the energy to drive the BC-FMT are transferred via an inductive link to the internal coil, processed by the demodulator and then relayed to the BC-FMT. The BC-FMT transduces the signal into mechanical vibrations, which are conducted to the mastoid bone via the cortical titanium screws. These vibrations stimulate the auditory system through the bone conduction pathway to allow the patient to hear.

VII. Intended Use & 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 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 3 kHz).
- 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 have experience with appropriately fit air conduction or bone conduction hearing aids.

VIII. Technological Characteristics

BONEBRIDGE is an active implantable bone conduction hearing system. BONEBRIDGE 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 BONEBRIDGE system do not affect the device intended use, fundamental operating principles or functional characteristics.

IX. Materials

The update to the EMC and MRI labelling of the BONEBRIDGE System does not affect the product materials which have been evaluated previously per 10993-1 and were shown to be biocompatible and safe for human use.

X. Performance Data

All necessary bench testing was conducted on BONEBRIDGE to support a determination of substantial equivalence to the existing BONEBRIDGE. The non-clinical bench tests supporting the labelling update included:

- Electromagnetic compatibility testing and
- MRI compatibility testing.

The collective results of the non-clinical testing demonstrate that BONEBRIDGE meets the established specifications to ensure consistent and safe performance for its intended use.

XI. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate system, BONEBRIDGE has been shown to be safe and effective for its intended use.