October 9, 2020

Med-El Elektromedizinische Geraete GmbH
Stephanie Haselwanter
Team Leader, Global Registrations, RA
Fuerstenweg 77a
Innsbruck, Tirol 6020
Austria

Re: K201983
Trade/Device Name: BCI 602 Lifts (1 mm), BCI Lifts (1 mm), BCI Lifts (2 mm & 3 mm), BCI Lifts (4 mm)
Regulation Number: 21 CFR 874.3340
Regulation Name: Active implantable bone conduction hearing system
Regulatory Class: Class I, reserved
Product Code: PFO
Dated: July 14, 2020
Received: July 17, 2020

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/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 Malvina Eydelman, M.D.
Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201983

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 has 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.

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

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K201983-510(k) Summary

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

I. Submitter

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II. Date Prepared

July 14th, 2020

III. Device

Trade Name:
BONEBRIDGE
BCI Lifts
- BCI 602 Lifts (1 mm)
- BCI Lifts (1 mm)
- BCI Lifts (2 mm & 3 mm)
- BCI Lifts (4 mm)

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

Trade Name:
BONEBRIDGE
BCI Lifts
- K191457
  - BCI 602 Lifts (1 mm)
- DEN170009

BCI Lifts (1 mm)
BCI Lifts (2 mm & 3 mm)
BCI Lifts (4 mm)

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

V. Purpose of Submission

The purpose of this premarket notification is to request clearance to update the materials of the BCI Lifts.

VI. Device Description

The BCI Lifts are optional accessories that can be implanted together with the BONEBRIDGE Bone Conduction Implant (model BCI 601 or BCI 602). They are attached to the fixation wings of the BCI and serve as a spacer to increase the distance between the fixation wings and the skull bone.

The devices can be used if the necessary drill depth for the BCI implant cannot be achieved for anatomical reasons. They are attached to the fixation wings of the BCI implant to reduce the necessary drill depth for the Bone Conduction - Floating Mass Transducer (BC-FMT) in the skull bone.

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 has 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 update to the materials of the BCI Lifts does not affect the BONEBRIDGE system intended use, fundamental operating principles or functional characteristics.

IX. Materials

The following new material is in direct and prolonged contact. The material has been evaluated per ISO 10993-1 and shown to be biocompatible and safe for human use:

- PEEK (polyetheretherketone).

In addition, performance testing has established the equivalence of the new BCI Lift material to the existing material. Overall, the testing performed demonstrates that the BCI Lifts made of PEEK are at least as safe and effective as the BCI Lifts made of PEKK.

X. Performance Data

In order to demonstrate the equivalence of the updated BCI Lifts with the existing BCI Lifts, the change of the material has been evaluated and tested to establish technical equivalence with the existing BCI Lifts.

Possible effects of the change on biocompatibility, sterilization and device performance were assessed as follows:

- Biocompatibility: The BCI Lifts made of PEEK have been evaluated and shown to be biocompatible.
- Sterilization: The BCI Lifts made of PEEK have been evaluated as per AAMI TIR28:2016 and it was concluded that the new Lifts can be adopted into the existing sterilization validation of the BCI Lifts (PEKK) without further study.
- Performance: The equivalence of the updated BCI Lifts to the existing BCI Lifts has been evaluated through bench testing as follows:
    - An assessment and comparison of the mechanical properties of the two materials was performed.
    - Performance testing was performed on BCI Lifts made of PEEK according to existing test methods.
    - Testing of the new BCI Lifts with the BCI implants was performed according to existing test methods that covered:
        - Torque/Force Stability
        - Dynamic Impact at 2.5J

It is concluded that the candidate BCI Lifts are substantially equivalent to the currently marketed predicate devices.

XI. Conclusion

Based on the indications for use, technological characteristics, and non-clinical bench testing results, the updated BCI Lifts have been shown to be substantially equivalent to the predicate

devices. The updated BCI Lifts are at least as safe and effective for their intended use as the predicate devices.