July 20, 2018

MED-EL Elektromedizinische Geraete GmbH
Elizabeth Gföller
Corporate Director, Regulatory Affairs
Fuerstenweg 77a
Innsbruck, 6020 Austria

Re: DEN170009
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: February 7, 2017
Received: February 16, 2017

Dear Elizabeth Gföller:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the BONEBRIDGE, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the BONEBRIDGE, and substantially equivalent devices of this generic type, into Class II under the generic name active implantable bone conduction hearing system.

FDA identifies this generic type of device as:

> **Active implantable bone conduction hearing system**. An active implantable bone conduction hearing 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On February 16, 2017, FDA received your De Novo requesting classification of the BONEBRIDGE. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BONEBRIDGE into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the BONEBRIDGE can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Dural erosion or compression resulting from failure to confirm adequate thickness and consistency of bone and related anatomy	Labeling
Surgical complications leading to • Bleeding/hematoma • Seizures • CSF leak • Implant damage or migration leading to revision/explantation	Clinical performance testing Labeling
Device software failure	Software verification, validation, and hazard analysis
Implant failure due to: • Fatigue • Damage/breakage • Loss of hermeticity	Clinical performance testing Non-clinical performance testing
Device failure to compensate for hearing loss	Clinical performance testing Non-clinical performance testing
Interference with other devices	Electromagnetic compatibility testing Wireless coexistence testing Electrical safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Infection	Sterilization validation Shelf life testing Labeling

In combination with the general controls of the FD&C Act, the active implantable bone conduction hearing system is subject to the following special controls:

1. Clinical performance testing must characterize any adverse events observed during implantation and clinical use, and must also demonstrate that the device performs as intended under anticipated conditions of use.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
    a. Performance data must validate force output in a clinically relevant model.
    b. Impact testing in a clinically relevant anatomic model must be performed.
    c. Mechanical integrity testing must be performed.
    d. Reliability testing consistent with expected device life must be performed.

3. The patient-contacting components of the device must be demonstrated to be biocompatible.

4. Performance data must demonstrate the sterility of the patient-contacting components of the device.

5. Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

6. Performance data must demonstrate the wireless compatibility, electromagnetic compatibility, and electrical safety of the device.

7. Software verification, validation, and hazard analysis must be performed.

8. Labeling must include the following:
    a. A summary of clinical testing conducted with the device that includes a summary of device-related complications and adverse events;
    b. Instructions for use;
    c. A surgical guide for implantation, which includes instructions for imaging to assess bone dimensions;
    d. A shelf life, for device components provided sterile;
    e. A patient identification card; and
    f. A patient user manual.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the active implantable bone conduction hearing system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Oldooz Hazrati at 240-402-9903.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health