



April 27, 2018

MED-EL Elektromedizinische Geraete GmbH
Elizabeth Gfoeller
Corporate Director, Regulatory Affairs
Fuerstenweg 77a
Innsbruck, AT 6020 Tirol

Re: K172460
Trade/Device Name: ADHEAR System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: March 23, 2018
Received: March 30, 2018

Dear Elizabeth Gfoeller:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Eric A. Mann -S

for Malvina 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)

K172460

Device Name

ADHEAR System

Indications for Use (Describe)

The ADHEAR system is intended to treat patients of all ages with conductive hearing loss or single-sided deafness via bone conduction. The ADHEAR system is a non-invasive bone conduction hearing device which is retained on the patient's head with an elastic headband or an adhesive adapter that is placed behind the auricle.

Indications:

- Unilateral or bilateral conductive hearing loss, either chronic or temporary.

The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 25 dB HL.

- Single-sided deafness (i.e. unilateral profound sensorineural deafness) with normal hearing on the contralateral side.

Normal hearing is defined as a pure tone average air-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 20 dB HL

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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K172460

510(K) SUMMARY

I. SUBMITTER

Applicant:

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Date Prepared: March 23, 2018

II. DEVICE

Trade Name:

ADHEAR System

Generic/Common Name:

Bone Conduction Hearing Prosthesis

Classification:

21 CFR§874.3300, Hearing Aid

Product Code:

LXB, Hearing Aid, Bone Conduction

III. PREDICATE DEVICES

- Contact Mini, audifon USA Inc. (K121793) Primary Predicate
- BAHA 5, Cochlear Americas (K142907) Secondary Predicate

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The ADHEAR system includes a bone conduction audio processor that can be retained on the head with an adhesive adapter or by the headband situated over the mastoid behind the auricle. The ADHEAR system is intended to be used during waking hours. While the adhesive adapter is attached to the skin for 3 to 7 days and then replaced, the audio processor is removed at night. Both the audio processor and the adhesive adapter are necessary components for the system to work. Together the components work as one system to deliver vibrations to the mastoid bone in order to conductively transmit sound to the inner ear for patients with conductive hearing loss or single sided deafness via bone conduction.

The ADHEAR system consists of an adhesive adapter sitting behind the auricle and an audio processor mounted on the attachment. The audio processor contains microphones and signal processing technology as well as a battery. It detects, processes, amplifies and finally transmits sound to the adhesive adapter which transmits vibrations to the mastoid which conducts sounds to the inner ear. The audio processor is equipped with a push button that allows the user to switch between 4 pre-defined settings. A colour sleeve is provided for pediatric use. It features a tamper-proof battery door and dampens potential drops of the processor unit.

The ADHEAR system contains the following components:

- ADHEAR Audio Processor (model 701)
- Package of ADHEAR Adhesive Adapters
- ADHEAR Positioning Tool
- ADHEAR Headband
- Retention clip
- ADHEAR Sleeves

V. INDICATIONS FOR USE

The ADHEAR system is intended to treat patients of all ages with conductive hearing loss or single-sided deafness via bone conduction. The ADHEAR system is a non-invasive bone conduction hearing device which is retained on the patient's head with an elastic headband or an adhesive adapter that is placed behind the auricle.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The ADHEAR System and the predicate devices are bone conduction devices intended to provide hearing improvement via bone conduction. They do so by inducing vibration using the same operating principle of receiving, amplifying, and transferring the sound via the bone of the skull to the inner ear of a unilaterally or bilaterally hearing impaired person.

At a high level the subject and predicate devices are based on the same technological elements:

- Audio processing unit with an electromagnetic transducer, generating vibration audible via bone conduction
- Coupling of the transducer via an elastic band pressing against the skull bone
- Battery powered using zinc-air batteries
- Digital audio signal processing to achieve acoustic amplification
- User controls
- Configurable via software
- Possibility to connect audio sources and ALDs (Assistive Listening Devices)

The following technological differences exist between the subject and predicate devices:

- Single-unit audio processing unit with snap coupling (identical to BAHA 5 but different to contact mini)
- Adhesive coupling option from the transducer to the skull bone
- No coupling option to a surgically implanted abutment (as found in the BAHA 5 predicate only)

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

BIOCOMPATIBILITY TESTING

The performed biocompatibility evaluation concludes that all identified biological risks have been adequately addressed for the ADHEAR System and its accessories according to ISO 10993-1:2009/AC:2010 and the FDA ISO 10993-1 guidance (FDA-2013-D-0350). The performed evaluation provides objective evidence to support the conclusion that the ADHEAR System and its accessories can be considered biocompatible for its intended use.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

Electrical safety, EMC and EMI testing were conducted on the ADHEAR System. The ADHEAR system complies with the applicable sections of the following standards: IEC 60601-1:2005 +A1:2012, IEC 60601-1-11:2015, IEC 60601-1-6:2010 +A1:2013, IEC 62366:2007 +A1:2014, IEC 60601-1-2:2014, and ANSI C63.19:2011.

MECHANICAL AND OTHER TESTING

Bench testing was successfully performed on the ADHEAR system in respect to the defined design specification requirements such as: Frequency range, OFL90, Maximum gain, Total harmonic distortion (THD), Equivalent input noise (EIN), Operating voltage, Current consumption, DAI connection, Signal processing features, Equivalent output noise (EON), Coupling distortion, Basic safety (general, EMC, usability, home healthcare environment), Removal force, Processor unit outer dimensions, Processor unit weight, Processor unit colors, Adhesive adapter colors, Batter door (battery size), Vibrator suspension, Tamper proof battery door, safety line, Push button operating force, Device marking, Drop test, Light exposure, Substance resistance, Power supply stability, Corrosion resistance, Change Battery, Switch device on/off, Adjust volume, change program, Change adhesive adapter, Place/Remove processor unit onto/from adhesive adapter, Push button longevity, DAI connector cycles, Battery door opening/closing cycles, and Protection during shipping

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

SOFTWARE VERIFICATION AND VALIDATION TESTING

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, since failures or latent flaws in the (optional) software are unlikely to result in any harm to the patient or operator.

CLINICAL TESTING

No clinical testing was needed to support the safety, performance, and substantial equivalence of the ADHEAR System to the predicate devices. All devices are bone conduction hearing aids and all aspects to ensure consistent and safe performance can be shown through non-clinical bench testing.

VIII. CONCLUSION

The non-clinical data provided support the safety of the device and the hardware verification and validation demonstrate that the ADHEAR System should perform as intended in the specified use conditions. The performance data has confirmed that the ADHEAR System is at least as safe and effective as the predicate devices, the Contact Mini and BAHA 5, and that the ADHEAR System is substantially equivalent to the predicate devices.