DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 16, 2016

Sophono, Inc.
Ms. Rozanne Paciej
Regulatory Affairs Project Manager
5744 Central Ave #100
Boulder, CO 80301

Re: K153391
Trade/Device Name: Sophono Bone Conduction Systems (S) Configuration and (M) Configuration
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 13, 2016
Received: May 16, 2016

Dear Ms. Paciej:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153391

Device Name
Sophono (S) & (M) Bone Conduction Hearing Systems

Indications for Use *(Describe)*
The Sophono® Sound Processor is intended for use with the Sophono® Headband (no age limitations), or with the Sophono® Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

• Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

• Bilateral fitting is applicable for most 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 4 kHz, or less than 15 dB at individual frequencies.

• Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).

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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Sophono™
bone conduction hearing solutions

510(k) Summary

Date summary prepared: 12/17/2015

510(k) Submitter/Holder:
Sophono Inc.
5744 Central Avenue #100
Boulder, CO 80301

Contact:
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Trade Name: Sophono® Bone Conduction Systems

Systems: Sophono® (S) Configuration
and Sophono® (M) Configuration

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid (21 CFR § 874.3300, Class II, LXB).

Predicate Devices:

Trade/Proprietary Name:	**Otomag Bone Conduction Hearing System (Primary Predicate)**
Common/Usual Name:	Bone Conduction Hearing System
Classification Name:	Hearing Aid
Class/Panel:	Class II, LXB, 21 CFR 874.3300
510(k) Submitter/Holder:	Sophono, Inc. 5744 Central Ave. #100 Boulder, CO 80301
510(k) #s:	K132189 (including K100193, K102199, K123962)

Trade/Proprietary Name:	Cochlear Baha® Auditory Osseointegrated Implant System: Model BI300 Implant and Model BA300 Abutment (Secondary Predicate)
Common/Usual Name:	Bone Conduction Hearing System
Classification Name:	Hearing Aid
Class/Panel:	Class II, LXB, 21 CFR 874.3300
510(k) Submitter/Holder:	Cochlear Americas 13059 E. Peakview Ave. Centennial, CO 80111
510(k) #:	K100360

Device Description

The Sophono® Bone Conduction Hearing Systems are a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations.

The Sophono® (S) configurations are held directly against the head using either a soft band or a headband with the Sophono™ Sound Processor. The vibration from the Sound Processor is transduced through direct contact with the patient's skin and the bone below.

The Sophono® (M) configuration is magnetically attracted to the Sophono® Sound Processor through a Magnetic Implant, and a Magnetic Spacer. The Magnetic Implant attracts a Magnetic Spacer that is held against the head through magnetic attraction forces to the Magnetic Implant, with the Sound Processor also held magnetically against the Magnetic Spacer. The vibration from the Sound Processor is transduced through direct contact with the patient's skin and the bone below to the inner ear.

The Sophono® Systems are designed for use for those patients with conductive hearing loss, those patients who have sensorineural hearing loss up to 45 dB in combination with their conductive loss, and single sided deafness as defined in the indications for use. The prescriptive formula and adjustments available to the audiologist in the software allow for programming the Sophono® Systems for individual patient hearing loss.

Indications for Use

The Sophono® Sound Processor is intended for use with the Sophono® Headband (no age limitations), or with the Sophono® Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

- Patients with conductive or mixed hearing losses, who can still benefit from amplification of sound. The pure tone average (PTA) bone conduction (BC) threshold for the indicated ear should be better than 45 dB HL (measured at 0.5, 1, 2, and 3 kHz).

- Bilateral fitting is applicable for most 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 4 kHz, or less than 15 dB at individual frequencies.

- Patients who have a profound sensorineural hearing loss in one ear and normal hearing in the opposite ear, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should be better than 20 dB HL (measured at 0.5, 1, 2, and 3 kHz).

Technological Characteristics

The Sophono® Bone Conduction Hearing Systems transmits audio vibrations through the skin into the bone where sound is sensed by the inner ear / cochlea.

In the Sophono® (S) configuration the Sound Processor is held against the head using a soft band or headband.

In the Sophono® (M) configurations the Magnetic Implant is magnetically attracted to the Sophono® Sound Processor through a Magnetic Spacer. The Magnetic Implant attracts a Magnetic Spacer that is held against the head through magnetic forces to the Magnetic Implant, with the Sound Processor magnetically attracted to the Magnetic Spacer. The vibration from the Sound Processor is transduced through direct contact with the patient's skin and the bone below.

The intended use, indications for use, function, and general fundamental technological operating principles of the devices have not changed.

Transcutaneous Energy Transfer (TET™) enables sound (vibration, energy) transfer from the Sophono® Sound Processor, through the patient's skin and magnetic bone implant, to the working cochlea.

Performance

Evidence of safety and effectiveness were obtained from bench testing, which included:

- Sterilization testing in accordance with ISO11135-1
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- Sterilization testing in accordance with EN 1422
- Biocompatibility testing in accordance with ISO 10993-1, ISO 10993-7
- Packaging testing in accordance with ISO 11607-2
- Electrical testing in accordance with IEC 60601-1
- Electromagnetic compatibility testing in accordance with IEC 60601-1-2
- Transportation testing in accordance to ISTA 2A
- Software verification and validation in accordance with IEC 62304
- ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2052-06e1, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213-06, (Reapproved 2011), Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2182-11a, Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2119-07, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- Engineering and functional testing including system, mechanical, electrical and general functional testing

Conclusion

The results of the testing demonstrate that the proposed Sophono® Bone Conduction Hearing Systems subject devices operated as intended and are substantially equivalent to the primary predicate subject device, Otomag Bone Conduction Hearing System.