K102199

MAY 2 3 2011

510(k) Summary: Otomag Bone Conduction Hearing System

This summary of substantial equivalence information is being submitted in accordance with the requirements set forth in 21 CFR 807.92.

Submitter: Sophono, Inc.

Establishment Registration Number: 3008514292

Contact Information:

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Date Prepared: May 20, 2011

Name of Device: Otomag Bone Conduction Hearing System

Common Name: Bone Conduction Hearing System

Classification Name: Hearing Aid

Device Classification:

- Classification: II
- Classification Panel: Ear, Nose and Throat
- Regulation Number: 874.3300
- Product Code: LXB

Predicate Device:

Otomag Bone Conduction Hearing System, Unmodified Version – K100193

Xomed Audiant Bone Conductor - K855059 / K861971

Device Description:

The Otomag Bone Conduction Hearing System is a family of sound processors and accessories that operate on the principle of bone conduction of sound vibrations. The Otomag System consists of two distinct configurations; Alpha 1 (S) and Alpha 1 (M). This 510(k) is being submitted to add the Alpha 1 (M) configuration to the existing product family.

In the Otomag Alpha 1 (S), the Otomag Sound Processor is attached magnetically to a headband or softband. The headband or softband holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below.

In the Otomag Alpha 1 (M), the Otomag Sound Processor is attached magnetically to an implanted magnet assembly. The magnetic field holds the sound processor against the head and vibration is transduced through direct contact with the patient's skin and the bone below. A variety of magnetic

spacers, each with a different magnetic strength, are provided with the Alpha 1(M) configuration to allow adjustment of the magnetic field strength that holds the sound processor against the head.

The magnetic implant of the system is provided clean and non-pyrogenic, but is not sterile. The implant is intended to be sterilized via steam sterilization at the healthcare facility immediately prior to implementation.

The Otomag System is 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 Otomag System for individual patient hearing loss.

Technological Characteristics:

The technological characteristics of the version of the Otomag Bone Conduction Hearing System are equivalent to those of the predicate device. Items that are identical between the modified version and the predicate are:

- Overall Device Performance
- Fundamental Technology (bone conduction)
- Software

Technological characteristics that are different between the modified device and the predicate are as follows:

- Patient contact materials: Addition of a titanium cased magnetic implant for attachment of the sound processor assembly to the patient's skin.
- Method of Sound Processor Attachment: Addition of a titanium cased magnetic implant for attachment.

Non-clinical and clinical performance testing and evaluation were used to support the safety and effectiveness of the modified device.

Device Indications For Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag 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 10dB 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).

Contraindications

Any factor that would cause a clinician to refer the patient for medical assessment will temporarily, or in some cases permanently, halt the process of hearing aid fitting. These factors include:

- A hearing loss of sudden onset;
- A rapidly progressing hearing loss;
- Pain in either ear;
- Tinnitus of sudden recent onset, or unilateral tinnitus;
- Unilateral or markedly asymmetrical hearing loss of unknown origin;
- Vertigo (e.g. dizziness)

Patients using the Alpha 1(M) configuration of the device, which utilizes a magnetic implant, should not undergo magnetic resonance imaging (MRI) without having the implant removed prior to scanning.

Performance Standards:

The design of the Otomag Bone Conduction Hearing System conforms to the following voluntary standards:

- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- FDA Memorandum #G95-1: Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
- ISO 17665-1:2006: Sterilization of Healthcare Products - Moist Heat - Part 1 Requirements for the Development, Validation, and Routine Control of Sterilization Process for Medical Devices
- ISO 17664-1:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15223-1:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
- AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- AAMI/ANSI ST8:2008, Hospital steam sterilizers
- AAMI/ANSI ST67:2003/(R) 2008,Sterilization of health care products – Requirements for products labeled "STERILE"
- AAMI / ANSI ST77:2006, Containment devices for reusable medical device sterilization
- AAMI/ANSI ST79:2006,A1:2008,A2:2009 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- AAMI/ANSI ST81:2004, Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ASTM F136 – 08e1: Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-06: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications

- IEC 60601-1-2:2007: Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Immunity (ESD, Radiated RF Electromagnetic Field Amplitude Modulated, Power Frequency Magnetic Field)

Non-Clinical Performance Testing:

The Otomag Bone Conduction Hearing System has been subjected to extensive safety and performance testing. Testing of the Otomag Bone Conduction Hearing System included verification and validation of the following;

- Simulated Use: Device Retention
- Simulated Use: Vibration Transmission Comparison Alpha 1(M) vs. Alpha 1(S)
- Software Validation
- Sound Processor Performance: Frequency Response
- Immunity (IEC 60601-1-2)
- Implant Performance after 3x Sterilization
- Autoclave Cycle Performance (Sterilization)
- Accelerated Aging: Magnet Retention
- Dislodgement Force: Normal and Tangential
- Accelerated Aging: Screw Retention

The testing information presented in this submission demonstrates the device's performance is substantially equivalent to the predicate devices.

Clinical Performance Testing:

Clinical data on eighty-six (86) Alpha 1(M) devices implanted into 57 patients ranging in age from 5 years to 67 years was submitted in support of the safety and effectiveness of the Alpha 1(M) configuration of the device. The mean follow up time for the study was 1.6 years from the time of implant, with a range of 0.5 years to 3.8 years. The study showed the following important results:

- No surgical or post-surgical infections or adverse events associated with implant were reported as a part of the trial.
- No tissue necrosis or other significant tissue problems were reported in any of the 57 subjects at any time in the trial.
- A small percentage of subjects (8%) showed some initial redness under the magnetic spacer after installing the Alpha 1 (M) sound processor assembly. These issues were resolved by changing the strength of the magnetic spacers. Data showed none of these patients had recurring problems with pressure points or reddening.
- None of the subjects complained of issues, either mild or severe, of external processor dislodgement.
- Unaided and aided hearing performance is shown in the following table

Measure	Unaided Air Conduction Thresholds	Unaided Bone Conduction Thresholds	Unaided Speech Understanding	Aided Speech Understanding	Free Field Gain	Aided Free Field Thresholds
Mean and Stdev	54+/- 12dB	16+/-10dB	4+/- 10%	86+/- 17%	38+/- 8db	16dB (calculated from unaided thresholds and free field gain)

Conclusion:

Based on the clinical and non-clinical performance testing, the modified version of the Otomag Bone Conduction Hearing System is safe and effective and considered to be substantially equivalent to the predicate Otomag device cleared in K100193 and the Audiant cleared K855059 and K861971.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 3 2011

Sophono Inc.
c/o Clay Anselmo
Reglera LLC
555 Zang Street
Lakewood, CO 80228

Re: K102199
Trade/Device Name: Sophono Otomag Bone Conduction Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: May 10, 2011
Received: May 13, 2011

Dear Mr. Anselmo:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

Enclosure

Indications for Use

510(k) Number: K102199

Device Name: Otomag Bone Conduction Hearing System

Indications for Use:

The Otomag Alpha 1 Sound Processor is intended for use with the Otomag Headband or Otomag Softband (no age limitations), or with the Otomag Osseointegrated Magnetic Implant (patients 5 years of age and up) for the following patients and indications:

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Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102199