K100193 page 1 of 2

5. 510(K) SUMMARY

MAY 18 2010

Applicant Name and Address: Sophono, Inc.
903 Brooklawn Dr.
Boulder, Colorado
80303

Establishment Registration Number: None at this time
Device Name: Otomag Bone Conduction Hearing System
Classification: 874.3300
Classification Name: Bone Conduction Hearing Aid
Product Code: LXB

Date Prepared: January 20, 2010

510(k) Contact Person and Phone Number:

Company: Mary Armstrong
555 Zang Street, Suite 100
Lakewood, CO
80228

Phone 303-223-4336
Fax 303-832-6700

Name and Address of Manufacturing Site:

Company: Otomag GmbH
Alte Dorfstrasse 67
D-32289 Rodinghausen
Germany

Manufacturing Site Contact Person and Phone Number:

Contact Name: Andreas Sentker

Phone: +49 05746/8504
Fax +49 05746/8578

Predicate Devices:

The Otomag Bone Conduction Hearing System is claimed to be substantially equivalent in material, design and function to the bone conduction versions of the following legally marketed predicate devices that utilize a headband and / or softband:

- Oticon Medical Ponto Pro Bone Anchored Sound Processor K090996
- Cochlear BAS Baha BP100 Sound Processor K090720

General 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 called the 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.

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.

Indications for Use:

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

The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.

Contraindications:

The Otomag Alpha 1 (S) Sound Processor connected to the Otomag Headband or Softband is contraindicated as follows;

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)

Summary of Technical Characteristics

The technical specifications of the Otomag Alpha 1 Sound Processor are substantially equivalent to the technical specifications of the predicate devices discussed in this 510(k).

Summary of Non-Clinical Testing

The non-clinical testing presented in this submission demonstrates the Otomag System's performance is substantially equivalent to the predicate devices.

Conclusion

The Otomag System is considered to be substantially equivalent in design, material and function to the bone conduction versions of the previously 510(k) (K090996 & K090720) cleared predicate devices that utilize a headband and / or softband, without raising new issues of safety and / or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Sophono, Inc.
c/o Mary Armstrong
Director of Regulatory Affairs
Reglera LLC
555 Zang Street, Suite 100
Lakewood, CO 80228

MAY 18 2010

Re: K100193
Trade/Device Name: Otomag Bone Conduction Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: April 12, 2010
Received: April 14, 2010

Dear Ms. Armstrong:

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: K100193

Device Name: Otomag Bone Conduction Hearing System

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The Otomag Alpha 1 (S) Sound Processor is intended to be connected to the Otomag Headband or Softband.

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

Prescription Use
(Per 21 CFR 801.109)

510(k) Number K100193