510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: January 13, 2011

510(k) number: K100649

JAN 14 2011

Applicant Information:

Sonitus Medical, Inc.
1825 S. Grant St., Suite 350
San Mateo, CA 94402
Telephone: (650) 838-0325
Fax: (650) 838-0326

Contact Person

Robert J. Chin
Phone Number: (650) 593-5225
E-mail: rjchin@pacbell.net

Device Information:

Trade Name:	SoundBite™ Hearing System by Sonitus Medical
Classification:	Class II
Classification Name:	Hearing Aid, Bone Conduction (Regulation: 21CFR; 874.3300, Product Code: LXB)

Physical Description:

The SoundBite Hearing System by Sonitus Medical consists of two main components; a behind the ear (BTE) microphone unit and an in the mouth (ITM) hearing device. Accessories include a system charger and programming software.

The BTE uses a digital signal processor to process the sound and a wireless chip to transmit the signals to the hearing device worn in the mouth. The ITM hearing device in turn creates imperceptible vibrations using a piezoelectric actuator that are sent via the teeth, through the skull bones, and ultimately to the cochleae.

Indications for Use:

The SoundBite prosthetic device is intended for the following patients and indications:

- Patients who are 18 years or older and have moderately severe, severe, or profound sensorineural hearing loss in one ear and normal hearing in the other ear (i.e. single sided deafness or "SSD"). Normal hearing is defined as a pure tone average (PTA) air-conduction (AC) hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of better than or equal to 25 dB HL.

Additionally, use of SoundBite is intended for patients with:

- At least two contiguous molar or premolar teeth with no untreated tooth decay. Patients with tooth decay present are to first have restorations before being fitted for SoundBite;
- Healthy attachment to those teeth with tooth pockets limited to no more than 5mm;
- No mobile teeth;
- Bone loss no greater than a 34% average on the mesial and distal sides of the tooth as measured on X-ray on the teeth on which the device will be worn.

Contraindications:

- The SoundBite Hearing System and all portions of it are contraindicated for use in an MRI Environment and should be removed prior to MRI exposure.
- The SoundBite Hearing System is not to be used in patients with known hypersensitivity to any of the components including allergies to polymers.
- The SoundBite Hearing System is contraindicated for vulnerable populations that are unable to use their hands such as paraplegics or others that are unable to comply with the warnings in the product's labeling.

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the Second Ear Bone Conduction Hearing Aid (K953872), the Baha Entific (K021837, K090720) and the Transear Bone Conduction Hearing Aid (K050653, K062404).

Conformance to Standards:

The SoundBite Hearing System complies with applicable portions of the following standards:

Electrical Safety, EMC and wireless

- IEC/EN 60601-1 (Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance)
- IEC/EN 60601-1-2 (Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance)
- IEC/EN 60601-1-4 (Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems)
- IEC 60529 (Classification of degrees of protection provided by enclosures)
- EN 301-489 Parts 1 and 3 (Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services;
- EN 300-330 Parts 1 and 2 (Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz)
- IEEE C95.1 (IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz)

Biocompatibility and Cleaning

- ISO 10993-1 (Biological Evaluation of Medical Devices – Part 1: Evaluation and testing)
- ASTM E 2314-03 (Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test))

Packaging and Labeling

- ANSI/AAMI/ISO 15223-1 (Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements)
- IEC 80416-3 (Basic principles for graphical symbols for use on equipment - Part 3: Guidelines for the application of graphical symbols)
- ASTM F 2503-08 (Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment)
- EN 980:2008 (Device Labeling Guidance)
- ASTM D4169-09 (Performance testing of shipping containers and systems)

Quality Systems

- 21 CFR 820 (Quality System Regulation)
- ISO 13485 (Medical devices – Quality management systems, requirements for regulatory purposes)
- ISO 14971 (Medical devices – Application of risk management to medical devices)

Test Results:

Results of biocompatibility, electrical safety, software and bench testing, including simulated use cleaning validation studies on the ITM and charger devices, demonstrate that the SoundBite Hearing System by Sonitus Medical is safe and effective for its intended use.

Two prospective clinical studies were performed in which the SoundBite Hearing System was shown to be safe and effective for addressing the condition of SSD. The first study was a one-month safety and efficacy study on 28 subjects; the second was a six-month long-term safety study on 22 subjects. All subjects had acquired SSD.

In the first study the primary efficacy endpoint was a 1.0 dB improvement in HINT score for the condition of speech front and noise to the better ear. An improvement in HINT score is indicated as a negative (-) dB value change. A change in the HINT score of -1 dB represents an improvement of corresponds to a 10% improvement in the ability to hear speech in noise. The mean score measured for this endpoint was a -2.5 ± 1.0 dB improvement in HINT, a score that significantly exceeds the target endpoint. There were no product related adverse events in the study.

In the second study, dental, audiological and comprehensive health criteria were evaluated over a period of six months. Dental outcome measures included calculus, periodontal probing, plaque index, bleeding index, gingival recession, structural changes, bone support changes and root resorption. Audiological measures included both changes in aided hearing thresholds and presence of audological product-related or procedure-related adverse events. Medical outcome measures included comprehensive otological examination results at six months as compared to Day One. There were no product- or procedure-related adverse events in the study, and comprehensive medical, audiological, and dental evaluations pre and post the study showed no changes as a result of the device.

Summary:

Based on the intended use, product, performance and software information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Sonitus Medical
% Bob Chin, Ph.D.
Regulatory Consultant
1825 S. Grant St., Suite 350
San Mateo, CA 94402

JAN 14 2011

Re: K100649
Trade/Device Name: SoundBite™ Hearing System by Sonitus Medical
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: December 22, 2010
Received: January 3, 2011

Dear Dr. Chin:

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,

Kesia Alexander

for 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 Statement

510(k) Number (if known): K100649

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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 K100649

Prescription Use X
(Per 21 CFR 801.109)