K080363

510(k) Summary

APR 10 2008

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided.

Submitted by:

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On behalf of:

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Date Submission Prepared:

January 21, 2008

Device Name:

Trade or Proprietary Name:	Baha® Cordelle II
Common or Usual Name:	Hearing Aid (Bone Conduction)
Classification Status:	Class II, 21 CFR §874.3300 Product Codes: LXB
Panel:	Ear Nose and Throat Specialty Panel

Predicate Devices

The design, manufacturing, function and fitting procedure of the Baha Cordelle II have not changed since it was originally cleared for marketing under 510(k) K992872. This submission is intended only for an expanded Indications for Use statement for this sound processor based on the additional gain/output it supplies relative to the other sound processors in the Baha family, and on published clinical data. See Table 2 under Section X of this submission for a detailed comparison of technological characteristics and features across the Baha family of sound processors used with the auditory osseointegrated implant.

Device Description

The Baha system works by combining a sound processor with an abutment and a small titanium implant placed in the skull behind the ear. The system is based on the process of "osseointegration" through which living tissue integrates with titanium in the implant. Thus, the titanium implant becomes one with the bone, allowing high-quality amplified and processed sound to be conducted via the skull bone directly to a cochlea with residual functionality.

The Cordelle II is one of three currently marketed sound processors for use with the Baha auditory osseointegrated implant. It is the only analog signal processing and body-worn sound processor, and it offers the highest power output of all the devices.

Intended Use

The Baha system is indicated for patients who have conductive or mixed hearing loss, and can still benefit from sound amplification. Patients with bilaterally symmetric conductive or mixed hearing loss may be implanted bilaterally. The Baha system is also indicated for patients with sensorineural deafness in one ear and normal hearing in the other ear (i.e. single-sided deafness; SSD), and patients who are candidates for an air-conduction contralateral routing of signals (AC CROS) hearing aid but who for some reason cannot or will not wear an AC CROS device.

Patients (either by themselves or with the aid of others) must be able to maintain hygiene of the abutment/skin interface of the Baha. They should also have sufficient bone volume and bone quality to support successful fixture placement.

Under 510(k) K992872, the Baha Cordelle II was cleared for marketing for conductive and mixed hearing loss patients with average bone-conduction thresholds of $\leq$ 45 dB HL (across 0.5, 1, 2, and 3 kHz), the same indication as all other previously and currently marketed Baha sound processors. However, since the Cordelle II offers substantially higher gain and maximum output than the other devices, an expanded indication of $\leq$ 65 dB HL is proposed with this submission.

Technological Characteristics

Baha Cordelle II is an external sound processor that utilizes analog signal processing with K-Amp circuitry (Killion, 1993) for use with the Baha auditory osseointegrated implant. It has substantially equivalent technology to previously marketed sound processors for the Baha system (Baha Compact, Baha Classic 300) and to the other two currently marketed Baha sound processors (Baha Divino, Baha Intenso™). The external sound processors of the Baha system differ in style, signal processing, features, and degree of available gain and output, but they are all interchangeable in that they snap to the abutment of the Baha auditory osseointegrated implant. Choice of processor(s) depends on the individual needs and desires of the patient. The Cordelle II is often chosen for a patient who has greater gain needs since it offers the highest output levels and K-Amp circuitry that helps prevent saturation.

Non-Clinical Tests

The manufacturing and development process for the Baha Cordelle II is in compliance with ISO 13485 (Medical devices. Quality management systems. Requirements for regulatory purposes); ISO 11137 (Sterilization health care products. Requirements for validation and routine control. Radiation sterilization); ISO 14971 (Medical devices. Application of risk management to medical devices); EN 552 (Sterilization of medical devices. Validation and routine control of sterilization by irradiation); EN 868-1 (Packaging materials and systems for medical devices which are to be sterilized. Part 1: General requirements and tests methods); EN 980 (Graphic symbols for use in the labeling of medical devices); EN 1041 (Information supplied by the manufacturer with medical devices); and ASTM F67-06 (Standard specification for unalloyed titanium for surgical implant applications).

Clinical Performance Data

Published data in the literature support the safety and efficacy of the Baha Cordelle II for the expanded audiometric fitting range in the proposed revised Indications for Use statement (van der Pouw *et al.*, 1998; Tjellstrom *et al.*, 2001; Bosman *et al.*, 2006; studies that were not sponsored by the applicant). The published data illustrate that the Cordelle II provides higher gain and maximum output levels than the other sound processors in the Baha family, and that patients with greater (more severe) degrees of bone-conduction hearing loss than previously cleared for marketing in the United States can also significantly benefit from the Cordelle II.

Conclusions

The design, manufacturing, function and fitting procedure of the Baha Cordelle II have not changed since it was cleared for marketing under 510(k) K992872, and testing of the Baha Cordelle II including inspectional, functional and environmental tests verify that the device meets the requirements in design specification and is substantially equivalent to previous Baha® auditory osseointegrated implant system sound processors cleared by the 510(k) process.

Bench testing, as well as recently published clinical performance data, support an expanded bone-conduction hearing threshold range in the Indications for Use statement for the Baha Cordelle II so that more patients can benefit from this technology.

References:

Bosman, AJ, Snik, AFM, Mylanus, EAM, Cremers, CWRJ (2006). *Fitting range of the BAHA Cordelle.* International Journal of Audiology; 45: 429-437.

Killion, M (1993). *The K-amp hearing aid: an attempt to present high fidelity to persons with impaired hearing.* American Journal of Audiology, 2: 52-74.

Tjellstrom, A, Hakansson, B, Granstrom, G (2001). *Bone-anchored hearing aids: Current status in adults and children.* Otolaryngologic Clinics of North America, 34(2): 337-363.

van der Pouw, CTM, Carlsson, P, Cremers, CWRJ, Snik, AFM (1998). *A new more powerful bone-anchored hearing aid: First results.* Scandinavian Audiology, 27: 179-182.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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APR 10 2008

Re: k080363
Trade/Device Name: Baha Cordelle II
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing aid, bone conduction
Regulatory Class: Class II
Product Code: LXB
Dated: February 8, 2008
Received: February 11, 2008

Dear Mr. Bundy:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

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

Enclosure

Indications for Use

510(k) Number (if known): K 080363

Device Name: Baha® Cordelle II

Indications for Use Statement:

The Baha Cordelle II sound processor is intended for use with the Baha auditory osseointegrated implant for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone-conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) should be better than or equal to 65 dB HL.

- Bilateral fitting of the Cordelle II is intended for patients who meet the above criterion in both ears, with bilaterally symmetric moderate to severe conductive or mixed hearing loss. Symmetrical bone-conduction thresholds are defined as less than a 10 dB average difference between ears (measured at 0.5, 1, 2, and 3 kHz), or less than a 15 dB difference at individual frequencies.

- Patients who suffer from unilateral sensorineural deafness in one ear with normal hearing in the other ear (i.e. single-sided deafness or "SSD"). 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.

- Baha for SSD is also indicated for any patient who is indicated for an air-conduction contralateral routing of signals (AC CROS) hearing aid, but who for some reason cannot or will not use an AC CROS.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Baha

ision Sign-Off)
ision of Ophthalmic Ear,
se and Throat Devises

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