

K07/606

AUG 28 2008

## 510(k) Summary

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:***

May, 2008

***Device Name:***

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

### ***Predicate Devices***

The design, manufacturing, function and fitting procedure of the Baha Intenso™ have not changed since it was marketed in 2007 using a Letter To file under 510(k) K042017 (Baha Divino). This submission is intended only for an expanded Indications For Use for this sound processor. The proposed expanded indication is based on bench testing showing that the gain/output of the Baha Intenso is greater than that for the Baha Divino™ sound processor, although the maximum output is less than that for the high-power body-worn processor, the Baha Cordelle II. See Table 2 and Figures 1 and 2 under Section IX 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 or Baha Headband.

### ***Device Description***

The Baha implant 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 Baha implant is cleared for use in children aged 5 and older, and in adults.

The Intenso is one of three currently marketed sound processors for use with the Baha auditory osseointegrated implant. It is the highest gain ear-level sound processor currently available, although the maximum output is less than that for the high-power body-worn sound processor.

Baha sound processors, including the Intenso, can also be used with the Baha Headband (or Softband). In this application there is no implantation surgery; Rather, the sound processor is attached firmly to the head using either the hard or soft headband, and the amplified vibrational sound is transmitted transcutaneously to the bones of the skull for transmission to the cochlea. The Baha Headband is suitable for use in patients of all ages.

### ***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.

For the Baha implant system, 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.

Via Letter To File under 510(k) K042017 (Baha Divino), the Baha Intenso sound processor has to date been marketed for conductive and mixed hearing loss patients with average bone-conduction thresholds only up to  $\leq 45$  dB HL (across 0.5, 1, 2, and 3 kHz), the same Indication For Use as the Divino sound processor. However, since the Intenso offers significantly higher gain/output than the Divino, and also offers feedback reduction circuitry, an expanded Indication For Use for the Intenso of  $\leq 55$  dB HL (average four-frequency bone-conduction threshold) is proposed with this submission.

### ***Technological Characteristics***

Baha Intenso™ is an external sound processor that utilizes digital signal processing with active feedback cancellation technology 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 Cordelle II). 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 all snap onto the abutment of the Baha auditory osseointegrated implant. Choice of processor(s) depends on the individual needs and desires of the patient. The Intenso is often chosen for patients who have greater gain needs than can be met with the Divino (i.e. those with mixed losses and poorer bone-conduction hearing thresholds), but who want the cosmetic discretion of wearing an ear-level device rather than the bulkier body-worn Cordelle II.

### ***Non-Clinical Tests***

The manufacturing and development process for the Baha Intenso 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 Divino for patients with average bone-conduction thresholds of  $\leq 45$  dB HL (e.g. Kompis *et al.*, 2007), and for the Cordelle II to average bone-conduction thresholds of  $\leq 65$  dB HL (e.g. Bosman *et al.*, 2006)). Because bench testing shows that the Baha Intenso can be placed between the other processors in terms of its gain/output (it has substantially greater gain/output than the Divino but less maximum output than the Cordelle II), we believe that further clinical performance data are unnecessary to prove that the Intenso can successfully fit average bone-conduction thresholds that are positioned midway between those of the other two currently marketed signal processors; i.e. up to average bone-conduction thresholds of  $\leq 55$  dB HL.

### ***Conclusions***

The design, manufacturing, function and fitting procedure of the Baha Intenso have not changed since it was marketed via Letter To File under 510(k) K042017 (Baha Divino), and testing of the Baha Intenso including inspectional, functional and environmental tests verify that the device meets the requirements in design specification and is substantially equivalent to previous Baha® sound processors cleared by the 510(k) process.

Bench testing supports an expanded bone-conduction hearing threshold range in the Indications for Use statement for the Baha Intenso, 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.

Kompis, M, Krebs, M, Hausler, R. (2007). *Speech understanding in quiet and in noise with the bone-anchored hearing aids Baha Compact and Baha Divino*. Acta Otolaryngol; 127(8): 829-835.



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AUG 28 2008

Cochlear Americas  
c/o Sean Bundy  
Regulatory Manager  
400 Inverness Parkway  
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Re: K081606  
Trade/Device Name: Baha® Intenso™  
Regulation Number: 21 CFR 874.3300  
Regulation Name: Hearing aid, bone conduction  
Regulatory Class: Class II  
Product Code: LXB  
Dated: June 4, 2008  
Received: June 6, 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.

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 081606

Device Name: Baha® Intenso

#### Indications for Use Statement:

The Baha Intenso™ sound processor is intended for use with the Baha auditory osseointegrated implant or Baha Headband 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 55 dB HL.
- Bilateral fitting of the Intenso 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. IV-1
- 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)

*Shulhan Peng*  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

Prescription Use   ✓    
(Per 21 CFR 801.109)

510(k) Number   K081606