K121317

Cochlear™ Hear now. And always

OCT 12 2012

6. 510(k) Summary

A. Submitter Information

Submitted by:	Cochlear Americas 13059 East Peakview Ave. Centennial, CO 80111
On behalf of:	Cochlear Bone Anchored Solutions AB Konstruktionsvägen 14 SE-435 33 Mölnlycke Sweden (Establishment Number 9616024)
Contact:	Sean Bundy Director of Quality and Regulatory Cochlear Americas sbundy@cochlear.com (303) 524-7139 (o) (303) 524-6825 (f)

B. Date Prepared

1-May-2012

C. Device Class

II

D. Device Name

Trade/Proprietary Name:	Cochlear™ Baha® Implant System
Common/Usual Name:	Auditory Osseointegrated Implant
Classification Name:	Hearing Aid, Bone Conduction, Implanted 21 CFR 874.3300, Class II
Classification Panel:	Ear Nose and Throat
Product Code:	MAH

E. Predicate Device:

Trade/Proprietary Name:	Cochlear™ Baha® Implant System
Common/Usual Name:	Auditory Osseointegrated Implant
Classification Name:	Bone Conduction Hearing Aid 21 CFR 874.3300, Class II
Classification Panel:	Ear Nose and Throat
Product Code:	LXB
510(k):	K100360

F. Purpose of Submission

The Baha implant system works by combining an external sound processor with an abutment and a small titanium implant placed in the skull behind the ear through a simple surgical procedure. The purpose of this Traditional 510(k) is to introduce slight modifications to the BA300 abutment (part of The Cochlear Baha BIA300 Series Implant System) cleared under 510(k) K100360. The modified abutment will be known as model BA400, and the system containing the abutment will be known as the 400 series. The other two parts that make the system function, the implant and the sound processors, will remain unchanged from what is legally cleared. The BA400 will be available as a standalone part or pre-mounted onto a Baha BI300 series titanium implant.

G. Device Description

The technology base for the Baha implant was originally derived from the 1952 discovery by Dr. Per-Ingvar Brånemark that titanium was biocompatible with bone, leading to the term "osseointegration". The Brånemark System, as it would later be known, formed the basis for the rapid development and widespread implementation of root form endosseous dental implants, now safely and effectively used by many hundreds of thousands of people worldwide. Root form dental implants share many characteristics with the Baha implant component including material, conformation, and surgical implantation procedures.

The Baha implant system functions by combining 3 parts: a titanium implant, a percutaneous abutment, and a sound processor. The system works by utilizing natural bone transmission as a pathway for sound to travel to the inner ear, bypassing the external auditory canal and middle ear. After surgical placement, the titanium implant naturally integrates with the skull bone over time through a process known as osseointegration. The external sound processor transmits sound vibrations through the percutaneous abutment to the titanium implant. The vibrating implant creates vibrations within the skull that stimulate the nerve fibers of the inner ear, allowing hearing.

The minor changes to this device are only to the abutment, the piece that serves as the connection between the osseointegrated implant and the external sound processor. The changes include a modified design and the addition of a hydroxyapatite coating, neither of which modify the intended functionality or fundamental operating principles of the implant/abutment system.

H. Intended Use

The Baha implant system is intended for treatment of patients who have conductive or mixed hearing loss as a result of certain medical conditions such as bilateral atresia and chronic supportive otitis media, and for those who have Single-Sided Deafness (SSD) caused by a congenital condition, surgery, trauma, or disease. The intended use of the system is to provide an osseointegrated fixation point for connection of an external sound processor. The abutment piece, the subject of this 510(k), is intended to provide a connection between the osseointegrated implant and the external sound processor. The intended use remains unchanged from the predicate device.

I. Technological Characteristics

The Baha implant system with the hydroxyapatite coated abutment has the same intended use, the same basic mechanical design, the same functional characteristics, the same fundamental operating principles, and is made of the same titanium as the predicate device.

J. Materials

Titanium according to ASTM F 67-06 Grade 4 USN R50700 (ISO 5832-2)
Hydroxyapatite: $Ca_5(PO_4)_3(OH)$ according to ISO 13779-2

K. Performance Data

Performance testing was conducted based on a comparison between proposed and predicate implant/abutment systems. The results were equal or better than established acceptance criteria, where predicate testing was used as a baseline.

L. Conclusion

Based on the indications for use, technological characteristics, and substantial equivalence comparison to the predicate device, the Baha Implant system with the hydroxyapatite coated abutments has been shown to be safe and effective for its intended use.

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

OCT 12 2012

Cochlear Americas
c/o Mr. Sean Bundy
Director of Regulatory Affairs and Quality
13059 East Peakview Avenue
Centennial, CO 80111

Re: K121317
Trade/Device Name: Cochlear Baha Implant System – BA400 Abutment
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: MAH
Dated: September 21, 2012
Received: September 24, 2012

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. 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.

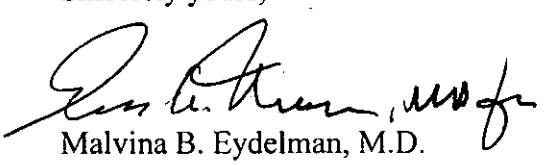
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

Cochlear™ Hear now. And always

5. Indications for Use Statement

510(k) Number (if known): K121317

Device Name: Cochlear ™ Baha® BA400 Abutment

Indications for Use:

The Cochlear Baha® auditory osseointegrated implant system using model BA400 abutment is intended for the following patients and indications for use:

- Patients aged 5 and older
- 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 3kHz) should be better than or equal to 45 dB HL for use with the BP100 sound processor, 55 dB HL for use with the Intenso sound processor, 55 db HL for use with the BP110 Power sound processor, and 65 db HL for use with the Cordelle II Sound Processor.
- Bilateral fitting 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-conductive 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 15dB 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: 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____ (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)

Daniel C Clapp

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121317