K121228

510(k) SUMMARY

SEP 7 2012

Oticon Medical's Ponto Bone Anchored Hearing System

Submitter name:	Oticon Medical AB
Address:	Ekonomiv. 2 SE-436 33 Askim Sweden
Establishment Registration #:	3007367732
Contact person:	Karolin Isberg Jernby
Telephone number:	+46 31 748 6153
Fax number:	+46 31 687 756
E-mail:	kai@oticonmedical.se

Date of submission:	2012-04-19
Device trade name:	Ponto Bone Anchored Hearing System
Common name:	Bone anchored hearing aid
Classification name:	Hearing aid, bone conduction, implanted
Classification regulation:	21 C.F.R. 874.3300
Product Code:	MAH

Predicate Devices

Trade name	Manufacturer
Ponto bone anchored hearing system (K112053).	Oticon Medical AB
Cochlear Baha BP100 (K090720)	Cochlear BAS

Intended Use

The Ponto bone anchored hearing system is intended for improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness.

Indications for Use

The Ponto bone anchored hearing system (sound processors Ponto, Ponto Pro and Ponto Pro Power and implant system) is intended for the following patients and indications:

- Patient with conductive or mixed hearing losses, who can still benefit from amplification of the sound. The pure tone average (PTA) bone conduction (BC) threshold (measured at 0.5, 1, 2 and 3 kHz) of the indicated ear should be better than or equal to 45 dB HL for use with the Ponto and Ponto Pro sound processors, 55 dB HL for use with the Ponto Pro Power sound processor.

- 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 10 dB 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 (i.e. single sided deafness or "SSD"). The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than or equal to 20 dB HL (measured at

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0.5, 1, 2 and 3 kHz).

- 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.

The placement of a bone anchored implant is contraindicated for patient below the age of 5.

The Ponto sound processors are intended to be used with the Ponto implant system (all models) or the Baha abutment snap coupling from Cochlear Bone Anchored Solutions (BAS) according to the below;

Ponto and Ponto Pro sound processors (130-00-212-00, 130-00-222-00, 130-00-112-00, 130-00-122-00, 130-00-211-00, 130-00-221-00, 130-00-111-00, 130-00-121-00, 130-00-210-00, 130-00-220-00, 130-00-110-00, 130-00-120-00, 130-00-911-00, 130-00-921-00, 130-00-910-00, 130-00-920-00, 130-00-113-00, 130-00-123-00, 130-00-213-00, 130-00-223-00) **Ponto Pro Power sound processors** (M50676, M50677, M50872, M50873, M50874, M70875, M50881, M50883, M50884, M50902, M50903, M50882)	**Compatible implant/abutments from Cochlear BAS** Baha abutment snap coupling 5.5mm (90305) Baha abutment snap coupling 8.5mm (90410) Flange fixture ST 4 mm with Baha abutment (90434) Flange fixture ST 3 mm with Baha abutment (90480) **Not compatible implant/abutments from Cochlear BAS** BA300 Series abutments (92126, 92127, 92130, 92131, 92346) BA210 Series abutments (92132, 92133, 92134, 92135)

In addition, the Ponto implant system can be used for connection of the Ponto sound processors (all models) or the Baha sound processors with snap coupling from Cochlear BAS according to the below;

Ponto implant system 3mm implants with pre mounted 6mm abutment (M50784) 4mm Implants with pre mounted abutment 6mm (M50358) 4mm Implants with pre mounted abutment 9mm (M50785) Wide implant, 4mm, with abutment 6mm (M51136) Wide implant, 4mm, with abutment 9mm (M51137) Wide implant, 4mm, with abutment 12mm (M51138) Wide implant, 3mm, with abutment 6mm (M51140) Wide implant, 3mm, with abutment 9mm (M51141) Abutments 6mm (M50349) Abutment 9mm (M50318) Abutment 12mm (M51149) Angled abutment (M50362)	**Compatible sound processors from Cochlear BAS** Baha sound processors with snap coupling: Baha Classic 300 snap (HCB-410-0, HCB-411-0, HCB-412-0) Baha Compact (90140, 90141, 90142) Baha Divino (90500, 90510, 90501, 90511, 90502, 90512, 90503, 90513) Baha Intenso™ (90730, 90731, 90732, 90733) Baha Cordelle (HCB 400-0, HCB 401-0, HCB 402-0) Baha BP100 (91300, 91301, 91302, 91303, 91304, 91305) Baha 3 Power BP110 (92840, 92841, 92842, 92843, 92844, 92845)

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Technological Characteristics

The Ponto bone anchored hearing system consists of an external sound processor unit and an implant with a skin penetrating abutment. The implant with the abutment is surgically anchored in the bone behind the ear. Vibrations generated by the sound processor are transmitted directly through the skull bone to the cochlea as bone conduction sound. The sound processor has a coupling so that it can be easily connected to and disconnected from the abutment by the user.

Performance Data

Pertinent dimensions of the Ponto abutment were designed to match the respective dimensions of compatible Cochlear Baha abutments in order to permit compatibility between the Cochlear Baha sound processors and Ponto abutments/implants, and also between Ponto processors and the above specified compatible abutments from Cochlear Bone Anchored Solutions. The Ponto sound processor and Ponto abutment have been tested in cross combination with the Baha sound processor with snap coupling and Baha abutment snap. Maximum release force, minimum retention force and vibration transmission has been tested both initially on new couplings and after wear. The testing verifies the performance of the Ponto sound processor both when used on the Ponto abutment and the Baha abutment snap. In all instances the Ponto sound processor functioned as intended and the coupling forces and vibration transmission was as expected. Testing also verifies equivalent performance of the Baha sound processor when connected to either the Ponto abutment or the Baha abutment snap.

Substantial Equivalence

The Ponto bone anchored hearing system is as safe and effective as the Baha system and previously cleared versions of the Ponto system. The Ponto system has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between the Ponto system and its predicate devices raise no new issues of safety or effectiveness. Thus, the Ponto system is substantially equivalent.

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

Oticon Medical AB
c/o Ms. Karolin Isberg Jernby
Quality Assurance & Regulatory Affairs Manager
Ekonomiv 2
SE-436 33 Askim
Sweden

SEP 7 2012

Re: K121228
Trade/Device Name: Ponto Bone Anchored Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing aid, bone conduction, implanted
Regulatory Class: Class II
Product Code: MAH
Dated: July 06, 2012
Received: July 11, 2012

Dear Ms. Jernby:

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,

Jessica 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

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Indications for use

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The placement of a bone anchored implant is contraindicated for patient below the age of 5.

The Ponto sound processors are intended to be used with either the Ponto implant system or with specific compatible Baha abutments/implants from Cochlear Bone Anchored Solutions (BAS) (refer to the Ponto labeling for specific compatible Cochlear models). In addition, selected Cochlear Baha sound processors can be used with the Ponto implant/abutment system (refer to the Ponto labeling for compatible Baha sound processor models).

Prescription Use __X_____ OR Over-The-Counter Use _____
(Part 21 CFR 801.109)

(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

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