



Food and Drug Administration
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January 22, 2016

Oticon Medical AB
Ms. Carolina Wessling
Quality Assurance and Regulatory Affairs Manager
Datavägen 37B
SE-436 32 Askim
Sweden

Re: K152820

Trade/Device Name: Ponto Bone Anchored Hearing System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: MAH
Dated: October 22, 2015
Received: October 26, 2015

Dear Ms. Wessling:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Y. Alexander -A

for 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

Indications for Use Statement

510(k) Number (if known): K152820

Device Name: Ponto Bone Anchored Hearing System

Indications for Use:

The Ponto bone anchored hearing system (Ponto sound processors 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, Ponto Pro and Ponto Plus sound processors, 55 dB HL for use with Ponto Pro Power and Ponto Plus Power sound processors.
- 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 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 patients 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
(Per 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(Per 21 C.F.R. 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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510(k) SUMMARY**Oticon Medical AB's Ponto bone anchored hearing system****Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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 Sweden

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Contact Person: Carolina Anker Wessling
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Date Prepared: November 25, 2015

Name of Device: Ponto bone anchored hearing system

Common or Usual Name: Hearing Aid, Bone Conduction

Classification Name: Hearing Aid, Bone Conduction / Hearing Aid, Bone Conduction, Implanted

Predicate Devices

510(k)	Device name	Manufacturer
K142678	Ponto bone anchored hearing system	Oticon Medical AB

Purpose of the 510(k) notice

The scope of this 510(k) submission is the addition of an abutment extension accessory to the Ponto bone anchored hearing system.

For existing patients: The abutment extension is to be used as a non-invasive extension for Ponto abutments or selected abutments from Cochlear BAS (refer to the Abutment extension labeling) in situations where the patient needs a longer abutment and as such a more invasive abutment change can be avoided or postponed. The abutment extension allows for connection of Ponto Sound Processors

For new patients / upon initial implant installation: It is recommended to use the appropriate abutment length from the beginning (refer to the Ponto labeling).

Intended Use

The **Ponto bone anchored hearing system** intended use is 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** (Ponto sound processors and implant system) is indicated 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, Ponto Pro and Ponto Plus sound processors, 55 dB HL for use with Ponto Pro Power and Ponto Plus Power sound processors.
- 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 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 patients 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).

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.

The technological characteristics of the Ponto bone anchored hearing system remain unchanged. The Abutment extension accessory added to the Ponto bone anchored hearing system is a non-invasive component to be mounted on the abutment as point of attachment for the Ponto sound processor. The Abutment extension can be used with Ponto abutments and selected abutments from Cochlear BAS. When attached to the abutment it allows for connection of Ponto sound processors.

Performance Data

The Ponto bone anchored hearing system with the addition of the abutment extension has been tested in comparison to the previously cleared device to verify the performance and to support safety and effectiveness. Performance data including the sound processor coupling connection force and sound transmission, as well as lever effect and MRI testing show that the modified Ponto bone anchored hearing system is as safe and effective as the previously cleared device.

Substantial Equivalence

The modified **Ponto bone anchored hearing system** has the same intended use and indications, the same principles of operation, and the same technological characteristics as the previously cleared **Ponto bone anchored hearing system** (K142678).

Performance data demonstrate that the modified device is as safe and effective as the previously cleared **Ponto bone anchored hearing system** and that the system will perform as intended during use. Thus, the **modified Ponto bone anchored hearing system** is substantially equivalent to its predicate device.