DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 23, 2015

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

Re: K152067
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 27, 2015
Received: October 30, 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,

Eric A. Mann -S

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): K152067

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 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___	AND/OR	Over-The-Counter Use____
(Per 21 C.F.R. 801 Subpart D)		(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)

510(k) SUMMARY

Oticon Medical AB's Ponto bone anchored hearing system

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter: Oticon Medical AB
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Contact Person: Carolina Anker Wessling
Phone: +46 76 168 63 32

Date Prepared: October 6, 2015

Name of Device: Ponto bone anchored hearing system

Common or Usual Name: Hearing Aid, Bone Conduction

Classification Name: Hearing Aid, Bone Conduction, Implanted

Predicate Devices

Primary predicate device:

510(k)	Device name	Manufacturer
K112053	OBC Bone Anchored Hearing System	Oticon Medical AB

Additional predicate devices:

K142678	Ponto Bone Anchored Hearing system/ Abutment, 14mm.	Oticon Medical AB
K121228	Ponto Bone Anchored Hearing System	Oticon Medical AB

Purpose of the 510(k) notice

The scope of this 510(k) submission is a modification to the 4.5 mm diameter Ponto implant, introducing Ponto BHX implants with a modified surface topography on parts of the implant. The purpose of the modification is to enhance osseointegration properties of the implant.

In addition, minor modifications have been made to surgical instruments for a less invasive surgical approach, i.e. Minimally Invasive Ponto Surgery (MIPS).

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 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 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).

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 substantially unchanged from the original design. A modification has been made to the 4.5 mm diameter implant, introducing Ponto BHX implants with a rougher surface topography on parts of the implant. The purpose of the modification is to enhance osseointegration properties of the implant.

In addition, minor modifications have been made to surgical instruments for a less invasive surgical approach, Minimally Invasive Ponto Surgery (MIPS), for installation of Ponto implants. Instead of a linear incision, a single circular incision is created by means of a biopsy punch equivalent in size to the implant/abutment, enabling access for placement of the implant in the bone.

Performance Data

The modified device has been tested in comparison to the previously cleared device to verify the performance to support safety and effectiveness. Surface characterization and performance data including drill performance and cutting ability and bone anchorage of the implant show that the modified device 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** (K112053, K121228, K142678). The only difference is the rougher implant surface topography on parts of the Ponto BHX implants, and the modified surgical instruments used for installation of Ponto implants through Minimally invasive Ponto surgery.

Performance data demonstrates 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.