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

December 9, 2013

Otiocon Medical AB
% Ms. Satu Hjärtstam
Quality Assurance and Regulatory Affairs Specialist
Ekonomivägen 2
Askim, Sweden SE-436 33

Re: K132775
Trade/Device Name: Ponto Plus and Ponto PlusPower
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing aid, bone conduction
Regulatory Class: Class II
Product Code: LXB
Dated: September 11, 2013
Received: September 13, 2013

Dear Ms. Hjärtstam:

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 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. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K132775

Device Name: Ponto Plus and Ponto Plus Power

Indications for use:
The Ponto Plus and Ponto Plus Power are 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 Plus sound processor, 55 dB HL for use with the Ponto Plus 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 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 Plus and Ponto Plus Power 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 Plus 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____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sageev George -S
2013.12.09 12:25:25 -05'00'

510(k) SUMMARY

Ponto Plus and Ponto Plus Power

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

Submitter name: Oticon Medical AB

Address: Ekonomiv. 2
SE-436 33 Askim
Sweden

Phone: +46 31 748 6100
Facsimile: +46 31 687 756

Contact Person: Satu Hjärtstam
Mobile phone: +46 735 44 98 13

Date Prepared: September 2, 2013

Name of Device and Name/Address of Manufacturer

Ponto Plus and Ponto Plus Power

Oticon Medical AB
Ekonomiv. 2
SE-436 33 Askim
Sweden

Common or Usual Name: Ponto bone anchored hearing system

Classification Name: Hearing aid, bone conduction

Classification Regulation: 21 C.F.R. §874.3300 (Product codes LXB, MAH)

Predicate Devices

Device	510(k) no.	Manufacturer
Ponto bone anchored hearing system	K090996 (Ponto Pro)	Oticon Medical AB
Ponto bone anchored hearing system	K103594 (Ponto Pro Power)	Oticon Medical AB
Air conduction hearing aid	Exempt from 510k.	Oticon A/S

Intended Use / Indications for Use

Intended use

The Ponto Plus sound processors are intended for improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness.

Indications for use

The Ponto Plus and Ponto Plus Power are 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 Plus sound processor, 55 dB HL for use with the Ponto Plus 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 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 Plus and Ponto Plus Power 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 Plus 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

Ponto Plus and Ponto Plus Power are modifications of the previously cleared Ponto Pro (K090996) and Ponto Pro Power (K103594) and represent the two latest sound processor models in the Ponto bone anchored hearing system. (Hereinafter referred to as the Ponto Plus sound processors or as the Ponto Plus family when referring to both models and Ponto Plus and Ponto Plus Power when referring to the 2 different models.) A bone anchored hearing system consists of a sound processor connected to an implant with a skin penetrating abutment. The implant is surgically anchored in the skull bone behind the ear. Vibrations generated by the sound processor are transmitted via the implant 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. Alternatively, it can be connected to head band accessories, to function as a conventional bone conductor. Using a computer based fitting system the sound processor can be adjusted to the patient's individual hearing requirements.

The Ponto Plus family utilizes wireless technology and can receive audio signals from external sources when used together with an optional accessory, Ponto Streamer, from Oticon A/S. Ponto Streamer can also be used as a remote control to adjust the volume of the sound processor, or to change the listening program. The Ponto Plus family is intended to be used with either the Ponto implant system or with specific compatible BAHA abutments/implants from Cochlear Bone Anchored Solutions (BAS).

The Ponto Plus sound processors include the same sound processing features as the currently marketed models but they have also been complemented with an updated sound processing feature for feedback cancellation, the Inium feedback shield. The Inium feedback shield is the same as included in the predicate Oticon A/S air conduction hearing aids legally marketed as class II, 510(k)-exempt devices. Also the transducer design in Ponto Plus sound processors has been optimized resulting in higher maximum output in the mid to high frequency range.

This submission also includes addition of an alternative surgical approach to the Surgical manual for the previously cleared Ponto implant system part of the Ponto bone anchored hearing system. The new surgical technique, referred to as tissue preservation surgery, is a minimally invasive technique that requires no or limited soft tissue removal.

Discussion of testing

Testing of the Ponto Plus family includes functional testing and firmware validation. The sound processors have been tested to (1) not emit excessive amounts of electromagnetic energy (EMC emissions); (2) operate as intended without performance degradation in the presence of an electromagnetic disturbance (EMC immunity). Also electroacoustical verification has been conducted including tests for battery voltage and current consumption, frequency range, Peak OFLs at 90, 60 and 50 dB SPL, total harmonic distortion and equivalent input noise. Performance of the more powerful transducer has been verified, as well as the functionality of the updated feedback cancellation system. Furthermore, tests were conducted to verify the compatibility and the wireless range between the Ponto Streamer and the Ponto Plus sound processors. The above mentioned tests verify that the Ponto Plus and the Ponto Plus Power are equivalent to the Ponto Pro and the Ponto Pro Power, respectively, and that the wireless communication via the Ponto Streamer is functionally equivalent to the same of the predicate Oticon A/S air conduction hearing aids legally marketed as class II, 510(k)-exempt devices. In all instances, the Ponto Plus sound processors functioned as intended and the performance observed was as expected. Hence we have come to the conclusion that further testing will not raise new issues of safety and efficacy.

Substantial Equivalence

The Ponto Plus and the Ponto Plus Power are as safe and effective as the Ponto Pro and the Ponto Pro Power sound processors. The Ponto Plus sound processors have the same intended use and indications, as well as principles of operation as their predicate devices. The wireless technology in the Ponto Plus sound processors is the same as the wireless technology used in the legally marketed, class II 510(k)-exempt Oticon A/S air conduction hearing aids except that the Ponto Plus sound processors function as receivers only, thus

they do not allow for binaural communication and wireless fitting. The minor technological differences between the Ponto Plus sound processors and their predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Ponto Plus sound processors are as safe and effective as Ponto Pro and Ponto Pro Power sound processors. Thus, the Ponto Plus and Ponto Plus Power are substantially equivalent.

Comparison table

	Ponto Plus / Ponto Plus Power (No K-number yet)	**Ponto Pro** (K090996) **/ Ponto Pro Power** (K103594)	**Oticon air conductive hearing aid with wireless technology** (legally marketed, class II 510(k)-exempt)
Intended Use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness.	Same	To amplify and transmit sound to the ear and hereby compensate for impaired hearing. Indicated for hearing losses within mild-to- severe-to-profound range.
Sound processing features	•15 sound processing channels • Multiband adaptive directionality • Speech Guard • Tri-state noise reduction • Wind noise reduction • Inium feedback shield	•15 sound processing channels •Multiband adaptive directionality • Speech Guard • Tri-state noise reduction • Wind noise reduction • Dynamic feedback cancellation	•15 sound processing channels •Multiband adaptive directionality • Speech Guard • Tri-state noise reduction • Wind noise reduction • Inium feedback shield + other features
Fitting features	•10 channel frequency response shaping • BC In-situ Audiometry • Feedback Manager • Data Logging • Technical Measurement tool • Verification tool • Ponto Streamer Settings tool	•10 channel frequency response shaping • BC In-situ Audiometry • Feedback Manager • Data Logging	•10 channel frequency response shaping • Feedback Manager • Data Logging • Technical Measurement tool • Verification tool • Streamer Pro Settings tool + other features
Wireless	Yes	No	Yes
Coupling	• Material: PEEK • Snap coupling outside the abutment	Same	N/A
Accessories	• Head band, test band and softband • Genie Medical fitting software • Xpress • Skins for personalization • Ponto Streamer	• Head band, test band and softband • Genie Medical fitting software • Xpress • Telecoil, Audio adapter, FM	Various accessories, including Genie fitting software and Oticon Streamer Pro
Safety Features	• Tamper proof battery door • Maximum coupling safety release force around 31 N	Same	N/A
Standards with which the Device Complies	• ISO 13485:2012 • 21 CFR Part 820 • 93/42/EEC • ISO 14971:2007 • IEC 60601-1-2 • IEC 60118-13 • EN ISO 10993-1:2009 • ISO 15223:2012 • EN 1041:2008 • 1999/5/EC (R&TTE)	• ISO 13485:2012 • 21 CFR Part 820 • 93/42/EEC • ISO 14971:2007 • IEC 60601-1-2 • EN 60118-13:2005 • EN ISO 10993-1:2004 • ISO 15223 • EN 1041:2008	N/A