DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 29, 2016

Oticon Medical AB
Ms. Satu Hjartstam
Quality Assurance and Regulatory Affairs Manager
Datavagen 37b
Askim, SE-436 32 SE

Re: K161671
Trade/Device Name: Ponto 3, Ponto 3 Power and Ponto 3 SuperPower
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: August 31, 2016
Received: September 2, 2016

Dear Ms. Hjartstam:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161671

Device Name
Ponto 3, Ponto 3 Power, Ponto 3 SuperPower

Indications for Use *(Describe)*
Intended use:
The Ponto 3 sound processors are intended for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single sided deafness.
Indications for use:
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower 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 3 sound processor, 55 dB HL for use with the Ponto 3 Power sound processor and 65 dB HL for use with the Ponto 3 SuperPower 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.
• Indicated for 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 3, Ponto 3 Power and Ponto 3 SuperPower 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 3 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).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY K161671

Ponto 3, Ponto 3 Power and Ponto 3 SuperPower

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

Submitter name: Oticon Medical AB

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Sweden

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

Date Prepared: Sep 15, 2016

Name of Device and Name/Address of Manufacturer

Ponto 3, Ponto 3 Power and Ponto 3 SuperPower

Oticon Medical AB
Datavägen 37 B
SE-436 32 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 Plus and Ponto Plus Power *(Primary predicate device)*	K132775	Oticon Medical AB
Baha Cordelle II *(Additional predicate device)*	K080363	Cochlear BAS AB
Alta 2 (Air conduction hearing aid) *(Additional predicate device)*	Exempt from 510k.	Oticon A/S

Intended Use / Indications for Use

Intended use
The Ponto 3 sound processors are intended for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single sided deafness.

Indications for use
Ponto 3, Ponto 3 Power and Ponto 3 SuperPower 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 3 sound processor, 55 dB HL for use with the Ponto 3 Power sound processor and 65 dB HL for use with the Ponto 3 SuperPower 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.

- Indicated for 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 3, Ponto 3 Power and Ponto 3 SuperPower 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 3 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 3, Ponto 3 Power and Ponto 3 SuperPower are modifications of the previously cleared Ponto Plus and Ponto Plus Power (K132775) and represent three latest sound processor models in the Ponto bone anchored hearing system. (Hereinafter referred to as the Ponto 3 sound processors or as the Ponto 3 family when referring to all three models and Ponto 3, Ponto 3 Power and Ponto 3 SuperPower when referring to the 3 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 3

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 3 family incorporates Inium Sense platform that is also used in the predicate Oticon A/S air conduction hearing aids legally marketed as class II, 510(k)-exempt devices. With the Inium Sense platform the microphone directionality system is updated. Furthermore, for Ponto 3 wireless transmission is enabled allowing for binaural signal processing.

In addition to the regular and power version sound processors, the Ponto 3 family introduces a SuperPower version with UltraDrive, consisting of a redesigned amplifier and optimized transducer. Ponto 3 SuperPower provides equivalent maximum force output (MFO) as the Baha Cordelle II, previously cleared through K080363, and thus expanded indication up to and including 65 dB HL is proposed.

This submission also includes minor modifications to the previously cleared accessories Genie Medical fitting software, Soft band and Streamer.

Performance data

Testing of the Ponto 3 sound processors includes functional testing and firmware validation.

Ponto 3 SuperPower 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) and ESD. 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. The current consumption and battery voltage have been verified for the Ponto 3 and Ponto 3 Power sound processors. The Ponto 3 and Ponto 3 Power hardware is identical to Ponto Plus and Ponto Plus Power hardware. Update from the previously cleared Inium platform to Inium Sense and addition of the new sound processing features do not affect the electromagnetic compatibility or acoustical performance and thus no new verification tests regarding EMC or electroacoustical performance have been carried out on the Ponto 3 and Ponto 3 Power sound processors. Furthermore, bench tests were conducted to verify the binaural coordination and updated microphone directionality system.

The above mentioned tests verify that the Ponto 3 sound processors are equivalent to the Ponto Plus sound processors and that the binaural signal processing and directionality features are functionally equivalent to the same of the predicate Oticon A/S air conduction hearing aids legally marketed as class II, 510(k)-exempt devices. Moreover, the maximum output force measurements show that the MFO and gain of the Ponto 3 SuperPower is equivalent or higher when compared to the output of the predicate Baha Cordelle II sound processor. In all instances, the Ponto 3 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 3 sound processors have the same intended use as the Ponto Plus sound processors and Ponto 3 and Ponto 3 Power have the same indications as the Ponto Plus and Ponto Plus Power, respectively. Ponto 3 SuperPower has the same indications as Ponto Plus Power, expect the bone-conduction hearing threshold that is 55 dB HL for Ponto Plus Power and 65 dB HL for Ponto 3 SuperPower. Indications of the Ponto 3 SuperPower are the same as those of the Baha Cordelle II. The principles of operation of the Ponto 3 sound processors are the same as those of the Ponto Plus sound processors.

The sound processing platform and the wireless technology in the Ponto 3 sound processors are the same as those used in the legally marketed, class II 510(k)-exempt Oticon A/S air conduction hearing aids. The maximum force output and gain of the Ponto 3 SuperPower are equivalent or higher in comparison to those provided by the Baha Cordelle II. The minor technological differences between the Ponto 3 sound processors and their predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Ponto 3 sound processors are as safe and effective as the Ponto Plus sound processors and that the Ponto 3 SuperPower is as safe and effective as the Baha Cordelle II sound processor. Thus the Ponto 3 sound processors are substantially equivalent.