May 2, 2019

Oticon Medical AB
Lise Terkelsen
Regulatory Affairs Manager
Datavagen 37 B
Askim, SE-436 32 Se

Re: K190540
Trade/Device Name: Ponto 4
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction, Implanted
Regulatory Class: Class II
Product Code: LXB, MAH
Dated: February 28, 2019
Received: March 4, 2019

Dear Lise Terkelsen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190540

Device Name
Ponto 4

Indications for Use *(Describe)*
Ponto 4 sound processors 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 4 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 4 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 4 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

Ponto 4

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

Submitter name: Oticon Medical AB

Address: Datavägen 37 B
SE-436 32 Askim
Sweden

Phone: +46 31 748 61 00
Facsimile: +46 31 687 756

Contact Person: Lise Terkelsen
Mobile phone: +45 24 22 51 46

Date Prepared: May 1, 2019

Name of Device and Name/Address of Manufacturer

Ponto 4

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
Predicate device: Ponto 3	K161671	Oticon Medical AB
Reference device: Oticon Opn S™ air conduction hearing aid with Bluetooth wireless connectivity	Exempt from 510k	Oticon A/S

Device Description

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 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).

Intended Use / Indications for Use

Intended use

The Ponto 4 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

Ponto 4 sound processors 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 4 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 4 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 4 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 4 is a modification of the previously cleared sound processors (the Ponto 3, Ponto 3 Power and Ponto 3 SuperPower in K161671), more specifically the Ponto 3 model, and represents the latest sound processor model in the Ponto bone anchored hearing system.

The Ponto 4 sound processor incorporates Velox S platform that is also used in the reference Oticon Opn S™ air conduction hearing aid legally marketed as class II, 510(k)-exempt devices. The Velox S platform introduces wireless 2.4 GHz Bluetooth connectivity and minor changes to the sound processing features, compared to the predicate Ponto 3. The Ponto 4 is smaller in size, which is enabled by moving the user controls to wireless accessories from Oticon A/S, and by smaller transducer and battery. Ponto 4 has a tamper resistant exchangeable battery drawer, side-neutral design, and a LED indicating status (e.g. low battery) of the sound processor.
The Ponto 4 housing and coupling are made of medical grade plastics that have been shown to be biocompatible and safe for human use.

This submission also includes minor modifications to the previously cleared accessory Genie Medical fitting software, and addition of compatibility with wireless accessories from Oticon A/S.

Discussion of testing

Testing of the Ponto 4 sound processors includes electroacoustic and EMC performance testing and firmware validation.

The Ponto 4 hardware is similar to Ponto 3 hardware, though smaller in size enabled by a smaller transducer and battery. The sound processing platform has been updated and a series of tests were conducted on the Ponto 4 sound processors to verify the design criteria and device performance with respect to electro acoustical performance. These tests include; Maximum output responses, Output for full-on gain at 50 dB SPL and 60 dB SPL, Equivalent input noise level, Total harmonic distortion, Frequency range, Battery voltage, Current Consumption, Battery lifetime, IRIL (input related interference level) and Processing delay, i.e. electro acoustical testing.

Ponto 4 sound processors have also 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.

The above-mentioned tests verify that the Ponto 4 sound processors are as safe and efficient as the Ponto 3 sound processors. In all instances, the Ponto 4 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 4 sound processors have the same intended use as the Ponto 3 sound processor in K161671.

Ponto 4 sound processors have the similar principles of operations as the Ponto 3 sound processors. The sound processor is connected via an abutment to an implant placed in the temporal bone behind the ear, and the vibrations from the sound processor are transmitted directly to the inner ear through bone conduction. The implant and abutment are installed by a surgical procedure, and the sound processor can be connected and disconnected by the user by the snap coupling.

The sound processor is individually adjusted to the patient audiogram and needs by the Genie Medical fitting software by the audiologist. The volume and listening program can be changed by the user. On the predicate Ponto 3 sound processors this is done either on the sound processor itself or via the wireless accessories, whereas on the Ponto 4 the user can change the volume and program by using wireless accessories only. The same wireless remote functions are available for the predicate Oticon A/S´s Oticon S™ air conduction hearing aids, legally marketed as class II, 510(k)-exempt devices.

The sound processing platform and the wireless technology in the Ponto 4 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 4 sound processor are equivalent to those provided by the predicate Ponto 3 sound processors.

Comparison table

	Ponto 4	Ponto 3 (K161671)	Oticon Opn S™ air conduction 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, whether unilaterally or bilaterally fitted or for those with 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.
Indications for Use	• 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 4 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 4 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 4 labeling for specific compatible Cochlear models). In addition, selected Cochlear Baha sound	Same	N/A

	processors can be used with the Ponto implant/abutment system (refer to the Ponto 4 labeling for compatible Baha sound processor models).		
Sound processing features	• Open Sound Navigator • Clear Dynamics • Transient Noise Management • Feedback Shield (LX) • 64 Processing channels • Speech Guard LX • Wind noise management • Battery management system • Fitting bandwidth of 10 kHz	• Free Focus • Multiband adaptive directionality • Tri-state noise reduction • Inium Sense feedback shield •15 sound processing channels • Speech Guard • Wind noise reduction • Binaural processing • Battery management system	Same (+ additional)
Fitting features	• 16 channel frequency response shaping • BC In-situ Audiometry • Feedback Analyser • OpenSound – Transition • OpenSound – Noise reduction controls • Wireless connection during fitting • Data Logging • Technical Measurement tool • Verification tool • FLogram • Wireless accessories setting tool • Visual indicators setting	•10 channel frequency response shaping • BC In-situ Audiometry • Feedback Manager • Data Logging • Technical Measurement tool • Verification tool • Streamer Settings tool (wireless accessory) • Fitting Assistant tool • FLogram	• 16 channel frequency response shaping • In-situ Audiometry • Feedback Analyser • OpenSound – Transition • OpenSound – Noise reduction controls • Wireless connection during fitting • Wireless accessories setting tool • Visual indicators setting
Wireless receiver / transducer	Receiver and transmitter, 2.4 GHz, Bluetooth	Receiver and transmitter, 3.84 Mhz, Oticon proprietary NearLink	Two wireless technologies with the commercial name TwinLink: Receiver and transmitter, 2.4 GHz, Bluetooth Receiver and transmitter, 3.84 MHz, Oticon proprietary NearLink
Coupling	• Material: PEEK • Snap coupling outside the abutment	Same	N/A
Accessories	Oticon Medical accessories: • Head band, test band, soft band and SoundConnector • Genie Medical BAHS fitting software, version 2019.1 • Skins for personalization Compatible wireless Oticon A/S accessories: • Oticon ON App • Remote control 3.0 • ConnectClip • TV Adapter 3.0 • EduMic	• Head band, test band, soft band and SoundConnector • Genie Medical fitting software, version 2016.1 • Skins for personalization Compatible wireless Oticon A/S accessories: • Connectline App • Oticon Medical Streamer Compatible wireless Oticon A/S accessories through the Oticon Medical Streamer: • Connectline TV Adapter • Connectline microphone • Connectline phone adapter	• Genie 2 fitting software • Oticon ON App • Remote control 3.0 • ConnectClip • TV Adapter 3.0 • EduMic
Safety Features	• Tamper proof battery drawer • Maximum coupling safety release force	• Tamper proof battery drawer • Maximum coupling safety release force	N/A

Conclusion

The minor technological differences between the Ponto 4 sound processors and their predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Ponto 4 sound processors are as safe and effective as the Ponto 3 sound processors. Thus, the Ponto 4 sound processors are substantially equivalent.