March 4, 2021

Oticon Medical AB
Carolina Wessling
RA Manager
Datavagen 37B
Askim, SE-436 32
Sweden

Re: K203807
Trade/Device Name: Ponto Bone Anchored Hearing System, MONO Surgery Kit
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: MAH

Dear Carolina Wessling:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated March 3, 2021. Specifically, FDA is updating this SE Letter (e.g., typo in the trade/device name).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shu-Chen Peng, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, 301-796-6481, Shu-Chen.Peng@fda.hhs.gov.

Sincerely,

Shuchen Peng -S

Shu-Chen Peng, Ph.D.
Assistant 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

March 3, 2021

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Trade/Device Name: Pronto Bone Anchored Hearing System, MONO Surgery Kit
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: MAH
Dated: February 2, 2021
Received: February 5, 2021

Dear Carolina 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Shu-Chen Peng, Ph.D.
Acting Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203807

Device Name

Ponto Bone Anchored Hearing System

Indications for Use *(Describe)*
The Ponto Bone Anchored Hearing System (Ponto sound processors and implant system) is intended for the following patients and indications:

• Patients 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 and Ponto 4 sound processors, 55 dB HL for use with the Ponto 3 Power sound processors 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.
• 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).

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

Oticon Medical AB's Ponto Bone Anchored Hearing System

Ponto Implant System, MONO Surgery Kit

Submitter: **Oticon Medical AB**
Datavägen 37B
SE-436 32 Askim
Sweden

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

Contact Person: Carolina Anker Wessling

Date Prepared: December 22, 2020

510(k) number: K203807

Name of Device: Ponto Bone Anchored Hearing System, Ponto Implant System, MONO Surgery Kit,

Common or Usual Name: Hearing aid, bone conduction

Classification Name: Hearing aid, bone conduction, implanted

Regulatory Class: 21 CFR §874.3300, Class II

Product Code: MAH

Predicate Devices

Predicate Device	510(k) no.	Manufacturer
Ponto Bone Anchored Hearing System	K152067	Oticon Medical AB

Device Description and purpose of the 510(k) notice

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 can be connected and disconnected by the user by the snap coupling. The technological characteristics of the Ponto Bone Anchored Hearing System, Ponto Implant System, remain unchanged from the original design (most recently cleared in K152067).

The Ponto Bone Anchored Hearing System also include accessories and instruments for installation of the implantable components, and the Ponto Surgical Manual and Surgical Manual Addenda include step by step instructions for a number of safe alternative surgical approaches for implant installation.

The main purpose of this 510(k) notification is a modification to the drilling to prepare the osteotomy for installation of a Ponto bone anchored implant, from two-step drilling (MIPS previously cleared in K152067) to a single drill step (MONO). The MONO Surgery Kit is a further development of the MIPS Surgery Kit previously cleared in K152067.

Intended Use / Indications for Use

Intended use
The **Ponto Bone Anchored Hearing System's** intended use is 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
The **Ponto Bone Anchored Hearing System** (Ponto sound processors and implant system) is intended for the following patients and indications:

- Patients 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 and Ponto 4 sound processors, 55 dB HL for use with the Ponto 3 Power sound processors 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.
- 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).

Summary of Technological Characteristics

Minor modifications have been made to the drills previously cleared in 510(k) K152067. In the MONO Surgery Kit, the guide drill is removed, and the widening drill is modified to enable a single drill step to prepare the osteotomy for Ponto implant installation.

The MONO drill is provided in a kit packaging together with Cannula, Insertion indicator and Soft healing cap. The Cannula, Insertion indicator and Soft healing cap components included in the MONO Surgery Kit are identical to those included in the previously cleared MIPS Surgery Kit (K152067).

The technological principle and characteristics of the Ponto Bone Anchored Hearing System, Ponto Implant System, remain unchanged from the original design (most recently cleared in K152067). No changes have been made to the implant components within the Ponto Bone Anchored Hearing System compared to previously cleared K152067.

Performance data

Pre-clinical bench tests were performed to compare the technical performance of the new drill against its precursors, that have proven to perform well in a clinical setting.

Comparative testing to install 4 mm Ponto implant (∅4.5 mm) in artificial bone using the MONO Surgery Kit and the predicate devices were performed. The testing included heat generation, insertion torque, installation turns, seating and measurements of ISQ-value at implant level. The results were according to the requirements and confirmed equivalence with the predicate drills/drill protocol.

The above-mentioned tests confirm that the MONO procedure and MONO Surgery Kit are as safe and efficient as the predicate MIPS procedure and MIPS Surgery Kit (K152067). In all instances, the modified instruments functioned as intended and the performance was as expected. Hence, it has been concluded that further testing will not raise new issues of safety and efficacy.

Substantial Equivalence Conclusions

The Ponto Bone Anchored Hearing System, including MONO Surgery Kit, is as safe and effective as the predicate Ponto Bone Anchored Hearing System (K152067). The Ponto Bone Anchored Hearing System has the same intended use and indications as previously cleared in K152067. Further, no changes have been made to the overall characteristics or principles of operation of the Ponto Bone Anchored Hearing System compared to the predicate device (K152067).

The minor technological differences between the MONO Surgery Kit and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the installation of Ponto Bone Anchored Hearing System implants using the MONO procedure is as safe and effective as the predicate installation procedures (K152067).

Accompanying documentation provide information on selection of surgical technique suited for the individual patient. The MONO Surgery Kit and MONO procedure do not alter the intended use of the Ponto Bone Anchored Hearing System and do not affect the safety and effectiveness of the Ponto Bone Anchored Hearing System when used as labelled.

Thus, the Ponto Bone Anchored Hearing System, including MONO Surgery Kit, is substantially equivalent to the previously cleared Ponto Bone Anchored Hearing System (K152067).

SUBSTANTIAL EQUIVALENCE CHART

	Predicate 510(k) K152067	This 510(k) K203807
Manufacturer	Oticon Medical AB	Oticon Medical AB
Intended Use	The Ponto system is intended for improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness.	The Ponto bone anchored hearing system's intended use is 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	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).	The Ponto bone anchored hearing system (Ponto sound processors and implant system) is intended for the following patients and indications: • Patients 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 and Ponto 4 sound processors, 55 dB HL for use with the Ponto 3 Power sound processors 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. • 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 / anatomical sites	The Ponto bone anchored hearing system consists of an external sound processor unit and an implant with a skin penetrating abutment. The implant is placed in or around the mastoid region of the skull on either one or both sides. The implant is then used as anchorage for the skin penetrating abutment that connects to the external sound processor. 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 easily be connected to and disconnected from the abutment by the user.	Same / No change

	Predicate 510(k) K152067	This 510(k) K203807
Implant system components	• Implants • Abutments • Connection screw • Healing cap • Cover screw	Same / No change
Intended use; Implant	The implants are intended to be placed in bone tissue for long term use (more than 25 years). The implants are intended to integrate with the bone tissue and provide a reliable anchorage for a sound processor.	Same / No change
Compatible sound processors	All Oticon Medical sound processors and selected sound processors from Cochlear Bone Anchored Solutions. *See Ponto labeling for compatible Baha sound processor models*.	Same / No change
Surgical instruments	Single use drills: • Linear incision drill (Guide drill / Wide Countersink) • MIPS Surgery Kit Reusable instruments	Single use drills: • Linear incision drill (Guide drill / Wide Countersink) • MIPS Surgery Kit • MONO Surgery Kit Reusable instruments
Implant system installation	Surgical procedure performed by an ENT surgeon.	Same / No change
Procedures for Ponto implant installation	Three (3) alternative procedures available: Linear incision, one-stage Linear incision, two-stage MIPS	Same, with addition of one (1) alternative procedure: MONO
Selecting procedure	**Linear incision, single-stage surgery is indicated for:** Adult patients with normal bone quality and thickness above 3 mm, where no complications during surgery are expected. Children with normal bone quality and a bone thickness above 4 mm (typically 12 years or older) provided that age, development status and other known factors have been considered and found suitable for single-stage surgery. **Linear incision, two-stage surgery is recommended for/when:** Adult patients with an expected bone depth below 3 mm or expected poor bone quality. (Reasons for expecting poor bone quality or thin bone may for example include disease or history of irradiation.) Children with a bone thickness below 4 mm, or where age development status or other factors make single-stage surgery unsuitable. An implant is placed in association with the removal of an acoustic neuroma. Contact with the dura mater or the wall of the sigmoid sinus is expected, or if there is any risk of complications. **MIPS surgical procedure is indicated for:** Adult patients with normal bone quality and bone thickness above 3 mm, where no complications during surgery are expected. Children with normal bone quality and a bone thickness above 4 mm (typically 12 years or older) provided that age, development status and other known factors have been considered and found suitable for single-stage surgery. Patients, as per above, with a skin thickness of 12 mm or less.	Same, with addition of: **MONO surgical procedure is indicated for:** Adult patients (18 years and above) with normal anatomy and expected bone thickness of at least 5mm, where no complications during surgery are expected. Patients, as per above, with a skin thickness of 12 mm or less. Use of MONO surgical technique is contraindicated for children and patients with expected bone thickness below 5 mm.
Implant material	Titanium, grade 4	Same / No change
Implant surface	Smooth titanium surface Laser ablation applied to parts of the thread valleys.	Same / No change

	Predicate 510(k) K152067	This 510(k) K203807
Implant manufacturing	Machine turning Laser ablation	Same / No change
Implant cutting properties	Self-tapping	Same / No change
Implant to abutment interface	Hexagon fit	Same / No change
Means of attaching the abutment to the implant	The abutment is fastened to the implant via an internal connection screw.	Same / No change
Packaging (sterile)	Peel open sterile pack	Same / No change
Sterilization method	Pre-sterilized by radiation (e-beam) sterilization	Same / No change
Single Use or Reusable	Single Use	Same / No change
Shelf Life	5 years	Same / No change