August 26, 2026

Oticon Medical AB
Anders Johansson
Director Quality & Regulatory Affairs
Datavägen 37 B
Askim, 43632
Sweden

Re: K261142
Trade/Device Name: Ponto 5 Mini; Ponto 5 Superpower
Regulation Number: 21 CFR 874.3302
Regulation Name: Bone-Conduction Hearing Aid
Regulatory Class: Class II
Product Code: MAH, LXB
Dated: August 6, 2026
Received: August 6, 2026

Dear Anders Johansson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SHUCHEN PENG -S

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261142

Device Name
Ponto 5 Mini
Ponto 5 SuperPower

Indications for Use *(Describe)*
The Ponto Implant system including Ponto sound processors 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 45 dB HL for Ponto 5 Mini or 65 dB HL for Ponto 5 SuperPower.
• 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 patients below the age of 5 years.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K261142

510(k) Summary

Prepared on: 2026-08-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Oticon Medical AB
Applicant Address	Datavägen 37 B Askim 43632 Sweden
Applicant Contact Telephone	+46701474262
Applicant Contact	Mr. Anders Johansson
Applicant Contact Email	arnj@oticonmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Ponto 5 Mini; Ponto 5 Superpower
Common Name	Bone-conduction hearing aid
Classification Name	Hearing Aid, Bone Conduction, Implanted
Regulation Number	874.3302
Product Code(s)	MAH, LXB (CLASS 2) - HEARING AID, BONE CONDUCTION

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K211640	Ponto 5 Mini	MAH
K213733	Ponto 5 Superpower	MAH

Device Description Summary

21 CFR 807.92(a)(4)

The Ponto sound processors converts sound into vibrations that are transmitted directly through the skull bone to the inner ear as bone conduction sound. The sound processor is connected to the skull bone behind the ear via a skin-penetrating abutment and an implant. The sound processor can also be connected to a non-surgical attachment solution, e.g. a softband, head band, test band. The principles with conduction is the same but the vibrations has to go through the skin as well.

The sound processor contains an electromagnetic transducer (vibrator), directional microphones and electronic amplifier. The sound processor is powered either by a standard zinc air hearing aid battery or a rechargeable NiHM coin cell battery.

The sound processor also includes 2.4 GHz wireless capabilities and is compatible with a range of connectivity accessories.

There are two models in the Ponto 5 sound processor family: Ponto 5 Mini and Ponto 5 SuperPower.

Intended Use/Indications for Use

21 CFR 807.92(a)(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).

The Ponto Implant system including Ponto sound processors 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 45 dB HL for Ponto 5 Mini or 65 dB HL for Ponto 5 SuperPower.
• 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 patients below the age of 5 years.

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).

Indications for Use Comparison 21 CFR 807.92(a)(5)

This modification does not affect the device's previously cleared intended use or indications for use, as established under Premarket Notifications K211640 and K213733.

Technological Comparison 21 CFR 807.92(a)(6)

The subject devices maintain the same fundamental technological characteristics as the predicate devices in all areas except for a limited modification to the power source. Specifically, the design, materials, chemical composition, mechanical configuration, principle of operation, and acoustic signal processing remain unchanged from the predicate devices.

The only modification introduced in the subject device is the option to operate the device using rechargeable nickel–metal hydride (NiMH) batteries in addition to the traditional zinc-air (ZnAir) batteries used in the predicate device. This modification does not alter the intended use, performance specifications or the device's underlying scientific technology.

The introduction of NiMH battery usage solely enables an alternative energy source and does not impact the functional design or any safety-critical systems of the device. Both battery types deliver power to the same internal electronic architecture, utilize the same sound processing algorithms, and preserve substantial equivalent device behavior under all operating conditions. Verification and validation activities confirm that the subject device performs comparably to the predicate when operated with either ZnAir or NiMH batteries.

Based on this assessment, the subject device is considered to have the same technological characteristics as the predicate device, with the sole exception of offering an optional rechargeable power source.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The modification to allow the optional use of rechargeable nickel-metal hydride (NiMH) batteries in the sound processor was evaluated in accordance with the manufacturer's design control and risk management procedures.

Non-clinical bench testing was performed to verify the impact of the battery option on device operation. Testing included operating time evaluation to confirm that the sound processor functions as intended when powered by rechargeable NiMH batteries and that performance is consistent with specified requirements. The results confirmed that operating time remains within acceptable limits and does not adversely affect device performance or usability. In addition, a documented engineering assessment and risk analysis were conducted to evaluate electrical compatibility and safety considerations associated with the use of rechargeable NiMH batteries compared to the previously cleared Zn-Air battery option. This assessment demonstrated that both battery types supply low-voltage DC power within the device's specified operating range, and that the device's internal power management circuitry ensures stable operation independent of battery chemistry. No additional non-clinical testing (e.g., EMT testing) was performed. Based on technical justification comparing Zn-Air and NiMH battery characteristics, the use of rechargeable NiMH batteries does not impact electromagnetic emissions or immunity. Therefore, the EMT safety summary remains unchanged.

No clinical testing was performed or required, as the change does not affect the device's intended use, clinical performance, acoustic output, or patient interaction.

Based on the non-clinical bench testing, engineering assessments, and risk management activities described above, the sound processor with the optional rechargeable NiMH battery remains as safe and effective as the legally marketed predicate device. The modification does not alter the intended use, fundamental scientific technology, or clinical performance of the device and does not introduce new questions of safety or effectiveness. All identified risks are adequately controlled and remain acceptable. Accordingly, the device is considered substantially equivalent to the predicate device and is appropriately submitted under the Special 510(k) pathway.