December 16, 2021

Oticon Medical AB
Anja Ravn
Regulatory Affairs Manager
Datavagen 37B
Askim, SE-436 32
Sweden

Re: K213733
Trade/Device Name: Ponto 5 SuperPower
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB, MAH
Dated: November 23, 2021
Received: November 26, 2021

Dear Anja Ravn:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213733

Device Name
Ponto 5 SuperPower

Indications for Use *(Describe)*

Ponto 5 SuperPower sound processors are 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 65 dB HL for use with the Ponto 5 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 – K213733

Oticon Medical AB's Ponto Bone Anchored Hearing System

Ponto Sound Processors, Ponto 5 SuperPower

Submitter: Oticon Medical AB
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Contact Person: Anja Ravn

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Date Prepared: December 10, 2021

Name of Device: Ponto 5 SuperPower

Common or Usual Name: Ponto Bone Anchored Hearing System

Classification Name: Hearing aid, bone conduction.

Regulatory Class: 21 CFR §874.3300, Class II

Product Code: LXB, MAH

Predicate Devices

Device	510(k) no.	Manufacturer
Ponto 3 SuperPower (Primary)	K161671	Oticon Medical AB
Ponto 5 Mini	K211640	Oticon Medical AB

Device Description and purpose of the 510(k) notice

The main purpose of this 510(k) notification is to include the Ponto 5 SuperPower sound processor in the Ponto 5 sound processor family, which is part of the Ponto Bone Anchored Hearing System.

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 sound processors are individually adjusted to the patient audiogram and needs via the Genie Medical BAHS fitting software by the Hearing Care Professional (HCP). The HCP connects the sound processors to the computer running the Genie Medical BAHS fitting software through either a wireless connection or a cable.

Ponto 5 SuperPower sound processor is a further development of and substantially equivalent to the primary predicate Ponto 3 SuperPower (K161671) and predicate Ponto 5 Mini (K211640).

As for both predicates, the Ponto 5 SuperPower sound processor is 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.

Ponto 5 SuperPower sound processor is indicated for hearing losses up to and including 65 dB HL (BC), same as the primary predicate Ponto 3 SuperPower sound processor.

Ponto 5 SuperPower sound processor includes the same sound processing platform and wireless technology as the predicate Ponto 5 Mini sound processor, enabling the same sound processing features and compatibility options as Ponto 5 Mini.

A minor updated hardware design (electronic and mechanic) is implemented in Ponto 5 SuperPower sound processor as compared to Ponto 3 SuperPower (K161671), to allow for a side neutral design that carries the same design and look as Ponto 5 Mini (K211640).

The functionality and features of the firmware in Ponto 5 SuperPower are the same as for predicate device Ponto 5 Mini, however updated in a new revision.

No functionality or features of the firmware are changed, added or removed by this update.

Other than the minor updates in hardware design and the very minor change to the firmware, the technological characteristics of the Ponto 5 sound processors remain unchanged from the original design (as latest cleared in K161671 for Ponto 3 SuperPower and K211640 for Ponto 5 Mini).

Additional purposes of this 510(k) notice is to include a minor modification to the accessory Genie Medical BAHS fitting software and to include the addition of Softband 5 to the Ponto Bone Anchored Hearing System:

- The fitting software is, as part of this 510(k), updated to include compatibility with Ponto 5 SuperPower in addition to Ponto 5 Mini and Ponto 4. No feature or functionality is changed, added or deleted in Genie Medical BAHS 2022.1, when compared to the current version Genie Medical BAHS 2021.2 (cleared together with Ponto 5 Mini in K211640).

- The Softband, previously cleared through K082108 and latest in K161671, consists of a band placed around the wearers head with a connector plate to which the sound processor is attached. The Softband can be used by patients in the pre-operative evaluation phase or as a long-term solution to benefit from the sound processor without having an implant (primarily children). The Softband can be used also bilaterally. The band and the connector plate have been modified for optimal comfort and use.

Intended Use / Indications for Use

Intended use
The Ponto Bone Anchored Hearing System is 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 5 SuperPower sound processors are 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 65 dB HL for use with the Ponto 5 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

The Ponto 5 SuperPower is a modification of the previously cleared sound processors, primary predicate Ponto 3 SuperPower (K161671) and predicate Ponto 5 Mini (K211640).

The electrical and mechanical design of Ponto 5 SuperPower includes minor modifications to size and shape in comparison to the predicate devices, Ponto 5 Mini and Ponto 3 SuperPower. The vibrator has the same topology as the Ponto 4/Ponto 5 Mini vibrator but is adjusted in size to adapt to needed power level. However, the fundamental electrical and mechanical design remain the same.

As the primary predicate device, Ponto 3 SuperPower, the Ponto 5 SuperPower is powered by a size 675P hearing aid battery (1.4 V) and includes a tamper resistant battery drawer, and local user control of listening volume and program change.

As the predicate device, Ponto 5 Mini, the Ponto 5 SuperPower incorporates wireless 2.4 GHz Bluetooth® Low Energy connectivity, side-neutral design, and a LED status indicator.

The sound processing platform in Ponto 5 SuperPower sound processor enables the same sound processing features as Ponto 5 Mini (K211640). No functionality or feature is changed, added or removed.

Ponto 5 SuperPower sound processor provides compatibility with the same range of wireless accessories as Ponto 5 Mini (K211640).

Summary of performance data

Performance data for the Ponto 5 SuperPower sound processors is produced using the same well-established methods as for primary predicate Ponto 3 SuperPower (K161671) and predicate Ponto 5 Mini (K211640).

The performance data includes software verification, electroacoustic verification, electrical and mechanical safety evaluation, electromagnetic compatibility (EMC) evaluation, and documentation of radio properties and performance.

Maximum Force Output is measured and found comparable for Ponto 5 SuperPower and primary predicate Ponto 3 SuperPower (K161671) in accordance with IEC 60118-9:2019 Electroacoustics - Hearing aids - Part 9: Methods of measurement of the performance characteristics of bone conduction hearing aids.

The performance data confirm that the Ponto 5 SuperPower sound processors are substantially equivalent compared to the primary predicate Ponto 3 SuperPower (K161671) and predicate Ponto 5 Mini (K211640).

Substantial Equivalence Conclusion

The Ponto 5 SuperPower sound processors have the same intended use as the primary predicate Ponto 3 SuperPower (K161671).

Ponto 5 SuperPower sound processors have similar principles of operations as the Ponto 5 Mini and Ponto 3 SuperPower 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.

As the predecessors, Ponto 5 SuperPower sound processors are individually adjusted to the patient audiogram and needs via the Genie Medical BAHS fitting software by the HCP. The HCP connects the sound processors to the computer running the Genie Medical BAHS fitting software. The sound processors are connected either via cable to Hi-Pro2 or ExpressLink (wired fitting equipment) or wireless using Noahlink (wireless fitting equipment) or the Oticon RemoteCare app.

Genie Medical BAHS 2022.1 and Ponto 5 SuperPower includes the same fitting options as the predicate device, Ponto 5 Mini with Genie Medical BAHS 2021.2 (cleared in K211640).

Comparison table

	Modified device **Ponto 5 SuperPower**	**Primary predicate device** **Ponto 3 SuperPower** (K161671)	**Predicate device** **Ponto 5 Mini** (K211640)
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 as for Ponto 5 SuperPower	Same as for Ponto 5 SuperPower
Indications for Use	• 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 65 dB HL. • 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).	Same as for Ponto 5 SuperPower	Same, **except** that patient's 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 (as opposed to the 65 dB HL for Ponto 3 SuperPower and Ponto 5 SuperPower).

	Modified device **Ponto 5 SuperPower**	**Primary predicate device** **Ponto 3 SuperPower** (K161671)	**Predicate device** **Ponto 5 Mini** (K211640)
	• 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).		
Sound processing features	OpenSound Navigator™ OpenSound Optimizer™ 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	FreeFocus (directionality system) Tri-state Noise Reduction Inium Sense feedback shield 15 sound processing channels Speech Guard Wind Noise Reduction Battery management system Binaural Processing Fitting bandwidth of 10 kHz	Same as for Ponto 5 SuperPower
Wireless features	Receiver and transmitter, 2.4 GHz, Bluetooth® Low Energy	Wireless connections to external devices through the Oticon Medical Streamer (using NFMI 3.84 MHz connection).	Same as for Ponto 5 SuperPower
Coupling features	Material: PEEK Snap coupling outside the abutment	Same as for Ponto 5 SuperPower	Same as for Ponto 5 SuperPower
Safety Features	• Tamper-resistant battery drawer • Maximum coupling safety release force	Same as for Ponto 5 SuperPower	• Tamper-resistant battery drawer option included in the sales package • Maximum coupling safety release force

	Modified device **Ponto 5 SuperPower**	**Primary predicate device** **Ponto 3 SuperPower** (K161671)	**Predicate device** **Ponto 5 Mini** (K211640)
Accessories	Oticon Medical accessories: • Head band, test band, softband and SoundConnector • Genie Medical BAHS fitting software, version 2022.1 • Skins for personalization Compatible wireless Oticon A/S/SBO Hearing A/S accessories: • Remote control 3.0 • ConnectClip • TV Adapter 3.0 • EduMic • Oticon ON app • Oticon RemoteCare app	Oticon Medical accessories: • Head band, test band, softband and SoundConnector • Genie Medical BAHS fitting software, version 2016.1 • Skins for personalization Compatible wireless Oticon A/S accessories: • Oticon Medical Streamer	Same as for Ponto 5 SuperPower *(Compatible with Genie Medical BAHS fitting software, version 2021.2 and 2022.1)*
Fitting options	Wired fitting: Hi-Pro 2 ExpressLink Wireless fitting: Noahlink wireless Oticon RemoteCare app	Wired fitting: Hi-Pro 2 ExpressLink	Same as for Ponto 5 SuperPower
Features in fitting software	16 channel frequency response shaping BC In-situ Audiometry Feedback Analyzer Data Logging Automatics (OpenSound settings, Transient Noise Reduction settings and Silencer Control) Single-sided deafness fitting mode Soft band fitting mode Wireless connection during fitting Wireless accessories setting tool Visual and audible indicators setting Technical Measurement tool Verification tool FLogram Program Manager Special Purpose Programs RemoteCare option	10 fitting frequency response shaping BC In-situ Audiometry Feedback Manager Data Logging Automatics (directionality mode and noise management) Single-sided deafness fitting mode Soft band fitting mode Fitting Assistant Wireless accessories setting tool (ConnectLine) Audible indicator setting Technical Measurement tool Verification tool FLogram Program Manager	Same as for Ponto 5 SuperPower

Conclusion

The Ponto 5 SuperPower is a modification of the previously cleared sound processors, primary predicate Ponto 3 SuperPower (K161671) and predicate Ponto 5 Mini (K211640).

The fundamental electrical and mechanical design remain similar to the predicate devices, Ponto 3 SuperPower and Ponto 5 Mini. The maximum force output of

the Ponto 5 SuperPower sound processor is equivalent to that provided by the predicate Ponto 3 SuperPower sound processor.

The minor technological differences between the Ponto 5 SuperPower sound processors and their predicate devices raise no new issues of safety or effectiveness. Using the same methods, the performance data for the Ponto 5 SuperPower sound processors demonstrate that they are as safe and effective as the predicate devices, Ponto 5 Mini and Ponto 3 SuperPower.

Therefore, it is concluded that the Ponto 5 SuperPower sound processors are substantially equivalent to the predicate devices, primary predicate Ponto 3 SuperPower (K161671) and predicate Ponto 5 Mini (K211640).