August 10, 2021

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

Re: K211640
Trade/Device Name: Ponto 5 Mini
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid
Regulatory Class: Class II
Product Code: LXB, MAH
Dated: July 9, 2021
Received: July 12, 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,

for Shu-Chen Peng
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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K211640

Device Name

Ponto 5 Mini

Indications for Use *(Describe)*

Ponto 5 Mini 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 45 dB HL for use with the Ponto 5 Mini 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)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY K211640

Oticon Medical AB's Ponto Bone Anchored Hearing System

Ponto Sound Processors, Ponto 5 Mini

Submitter: Oticon Medical AB
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Contact Person: Anja Ravn

Mobile phone: +45 26774422

Date Prepared: August 8, 2021

Name of Device: Ponto 5 Mini

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
Predicate device: Ponto 4	K190540	Oticon Medical AB
Reference device: Oticon Opn S™ air conduction wireless hearing aid	Exempt from 510(k)	Oticon A/S

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.

Ponto 5 Mini is a further development of the Ponto 4, cleared in K190540.The main difference between Ponto 5 Mini and Ponto 4 is a modification to the firmware in the Ponto 5 sound processors to additionally include the sound processing feature OpenSound™ Optimizer and an added compatibility with Oticon RemoteCare App from SBO Hearing A/S. Other than the minor changes to the firmware and compatibility, the technological characteristics of the Ponto 5 sound processors remain unchanged from the original design (most recently cleared in K190540).

Additionally, minor modifications to the accessory Genie Medical BAHS fitting software are made (e.g., added compatibility with Oticon RemoteCare App, addition of special purpose programs, and inclusion of DSL BC).

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 Mini 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 45 dB HL for use with the Ponto 5 Mini 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 Mini is a modification of the previously cleared sound processor, Ponto 4 (K190540), and represents the latest sound processor model in the Ponto Bone Anchored Hearing System.

The electrical and mechanical design of Ponto 5 Mini is unchanged from the predicate device, Ponto 4.

As the predicate device, Ponto 5 Mini is powered by a size 312 hearing aid battery (1.4 V) and incorporates wireless 2.4 GHz Bluetooth Low Energy connectivity, an exchangeable battery drawer for tamper resistant option, side-neutral design, and LED status indicator.

The firmware in Ponto 5 Mini sound processor includes an addition of the sound processing feature OpenSound™ Optimizer to the feedback management system. This sound processing feature introduces no new risk. Also, it does not alter or contributes to existing risks.

Further, Ponto 5 Mini sound processor adds to the list of compatible wireless accessories by including compatibility with the Oticon RemoteCare App from SBO Hearing A/S. This provides the option for remote appointments with the Hearing Care Professional (HCP). This possibility introduces no new risk, nor does it alter or contributes to existing risks.

Discussion of performance data

Performance data for the Ponto 5 Mini sound processors is produced using the same methods and acceptance criteria as for Ponto 4.

Electroacoustic verification includes 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. The results were according to requirements and equivalent to the performance of the predicate device, Ponto 4.

Ponto 5 Mini sound processors have been evaluated and found to have the same electrical and mechanical safety, electromagnetic compatibility (EMC), and radio properties and performance, that was established for the predicate, Ponto 4.

The above-mentioned performance data confirm that the Ponto 5 Mini sound processors are as safe and efficient as the Ponto 4 sound processors. In all instances, the Ponto 5 Mini sound processors functioned as intended and the performance observed was as expected. It is therefore concluded that further testing will not raise new issues of safety and efficacy.

Substantial Equivalence Conclusion

The Ponto 5 Mini sound processors have the same intended use as the Ponto 4 sound processor in K190540.

Ponto 5 Mini sound processors have the similar principles of operations as the Ponto 4 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 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 through either a wireless connection to a Noahlink (wireless fitting) or a cable and a Hi-Pro 2 or ExpressLink (wired fitting).

Genie Medical BAHS 2021.2 and Ponto 5 Mini includes the same fitting options for the HCP as the predicate device, Ponto 4 with Genie Medical BAHS 2019.1 (cleared in K190540), as well as an option for remote wireless fitting through compatibility with Oticon RemoteCare App from SBO Hearing A/S. The same remote wireless fitting option is available for the reference device

Oticon A/S´s Oticon Opn S™ air conduction hearing aids and all other Oticon devices on Velox S and Polaris platforms, legally marketed as class II, 510(k)-exempt devices.

As on the predicate Ponto 4 sound processors, volume and listening programs can be operated by the user via wireless accessories (incl. the Oticon On App).

Comparison table

	Modified device	**Predicate device**	**Reference device**
Name	**Ponto 5 Mini**	**Ponto 4** (K190540)	**Oticon Opn S™ air conduction hearing aid** (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	The hearing aid is intended to amplify and transmit sound to the ear.
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 45 dB HL for use with the Ponto 5 Mini 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.	Same	Impaired hearing within mild to severe-to-profound hearing loss

	Modified device	Predicate device	Reference device
	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 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 OpenSound™ Optimizer	OpenSound™ 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	Same (+ additional)
Wireless features	Receiver and transmitter, 2.4 GHz, Bluetooth Low Energy	Same	Two wireless technologies with the commercial name TwinLink: - Receiver and transmitter, 2.4 GHz, Bluetooth Low Energy - Receiver and transmitter, 3.84 MHz, Oticon proprietary NearLink
Coupling features	Material: PEEK Snap coupling outside the abutment	Same	N/A
Safety Features	• Tamper proof battery drawer • Maximum coupling safety release force	• Tamper proof battery drawer • Maximum coupling safety release force	N/A
Accessories	Oticon Medical accessories: • Head band, test band, softband and SoundConnector • Genie Medical BAHS fitting software, version 2021.2 • Skins for personalization Compatible wireless Oticon 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 2019.1 and 2021.2 • Skins for personalization Compatible wireless Oticon A/S accessories: • Remote control 3.0 • ConnectClip • TV Adapter 3.0 • EduMic • Oticon ON App	Oticon A/S accessories: • Genie 2 fitting software Compatible wireless Oticon A/S accessories: • Remote control 3.0 • ConnectClip • TV Adapter 3.0 • EduMic • Oticon ON App • Oticon RemoteCare App

	Modified device	Predicate device	Reference device
Fitting options	Wired fitting: Hi-Pro 2 ExpressLink Wireless fitting: Noahlink RemoteCare App	Wired fitting: Hi-Pro 2 ExpressLink Wireless fitting: Noahlink	Wired fitting: Hi-Pro 2 ExpressLink Wireless fitting: Noahlink RemoteCare App
Features in fitting software	16 channel frequency response shaping BC In-situ Audiometry Feedback Analyzer OpenSound™ – Transition OpenSound™ – Noise reduction controls Wireless connection during fitting Wireless accessories setting tool Visual indicators setting Data Logging Technical Measurement tool Verification tool FLogram Special Purpose Programs RemoteCare option	16 channel frequency response shaping BC In-situ Audiometry Feedback Analyzer OpenSound™ – Transition OpenSound™ – Noise reduction controls Wireless connection during fitting Wireless accessories setting tool Visual indicators setting Data Logging Technical Measurement tool Verification tool FLogram	16 channel frequency response shaping In-situ Audiometry Feedback Analyzer OpenSound™ – Transition OpenSound™ – Noise reduction controls Wireless connection during fitting Wireless accessories setting tool Visual indicators setting Special Purpose Programs RemoteCare option

Conclusion

The electrical and mechanical design of Ponto 5 Mini is unchanged from the predicate device, Ponto 4. The maximum force output and gain of the Ponto 5 Mini sound processor are equivalent to those provided by the predicate Ponto 4 sound processor. The minor technological differences between the Ponto 5 Mini sound processors and their predicate devices raise no new issues of safety or effectiveness. Using the same methods and success criteria, the performance data for the Ponto 5 Mini sound processors demonstrate that they are as safe and as effective as the Ponto 4 sound processors. Therefore, it is concluded that the Ponto 5 Mini sound processors are substantially equivalent to the Ponto 4 sound processors.