K103594

JUN 15 2011

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Oticon Medical summary for the Ponto Pro Power bone anchored sound processor.

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DATE OF SUBMISSION:	December 1, 2010

1. **Identification of device**

Proprietary Name:	Ponto Pro Power
Common Name:	Hearing Aid, Bone Conduction
Classification Status:	Class II per regulations 21 CFR § 874.3300
Product Code:	LXB

2. **Equivalent devices**

Oticon Medical believes that the Ponto Pro Power, regarding intended use, function, procedure and fitting, is substantially equivalent to the Ponto and Ponto Pro cleared in K082108 and K090996. The indications for use are equivalent to the Baha® Intenso™ cleared in K081606. The ability to measure bone-conduction thresholds directly via pure tones generated by the sound processor (BC In-Situ Audiometry), is substantially equivalent to the Baha® BP100 in K090720.

3. **Description of the device**

Ponto Pro Power is a bone conduction hearing aid which is connected to an implant with a skin penetrating abutment which has been 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. Ponto Pro Power has a coupling so that it can easily be connected and disconnected from the abutment by the user or alternatively from a head band accessory, to function as a conventional bone conductor. Using a computer based fitting system, Genie Medical; Ponto Pro Power can be adjusted to the patient's individual hearing requirements. Ponto Pro Power contains a number of advanced features:

- **Wind Noise Reduction** – Depending on the wind noise level, sounds will be attenuated. The more wind, the more attenuation. In Ponto Pro Power the Wind Noise Reduction system will – in addition – force the instrument into Omni directionality mode.
- **Feedback Management System** – The Feedback Management System consists of two parts: Feedback Manager and Dynamic Feedback Cancellation.
  - The Feedback Manager is a tool in Genie Medical that measures and applies feedback limits in the sound processor. The feedback limits are set to prevent static feedback and to facilitate the full use of the entire range of the volume control without feedback.
  - Dynamic Feedback Cancellation (DFC) is a feature in the sound processor that constantly checks for the presence of acoustic feedback. When feedback is detected, the DFC system phase cancels the feedback signal. DFC is designed to minimize the risk of feedback by adapting to sudden acoustical changes.
- **Automatic Gain Control** – Ponto Pro Power has an Automatic Gain Control that adjusts the gain to the environment. The Automatic Gain Control can work both over the whole frequency range and in each of the 10 frequency bands. There is an output AGC that ensures there is no distorted peak clipped signal at saturation level of the instrument. A peak clipped signal distorts the sinus signal. By avoiding this distortion, increased sound comfort is achieved.
- **Speech Guard** – Speech Guard is a signal processing system that works by maintaining linear processing as much as possible, but at the same time responding instantaneously to rapidly occurring environmental sounds – Speech Guard is designed to produce less distortion than traditional compression systems.
- **BC In-situ Audiometry** – BC In-situ Audiometry is a tool in Genie Medical for measuring the patient's bone conduction hearing thresholds directly via the sound processor.
- **Automatic Multiband Adaptive Directionality** – The system analyzes information from various environmental detectors and automatically chooses one of the three different directionality modes with the aim of automatically offering an improved speech to noise ratio in adverse listening situations. The directionality modes are Omni, Split Directionality and Full Directionality.
- **Tri-state Noise Reduction** – The Tri-state Noise Reduction system continuously analyzes the environment and aims at providing the appropriate amount of attenuation in different listening environments. It includes the detection of speech, environmental background noise and wind noise. The system automatically moves seamlessly between the different states. The aim of this system is to provide some degree of comfort in noisy environments while preserving the information most important for speech intelligibility.
- **Data Logging** – Data Logging permits the Ponto Pro Power to memorize listening levels, usage time, user settings and system states. The data can be analyzed externally, providing the audiologist and the patient with valuable information. The Information can be used to adjust the system settings in order to optimize patient comfort and speech intelligibility in any complex listening situation.
- **Learning Volume Control** – The Learning Volume Control enables the hearing system to adjust automatically to patient preferences over time. Different listening situations and preferred volume settings are memorized. The system continuously analyzes listening situations and automatically adjusts the volume to the memorized preferred setting. In this way the system assists to get the preferred volume for the patient without his/hers manual adjustment of the volume control.

The sound processor is intended to work with the Oticon Medical bone anchored implant system or the Baha Abutment snap coupling from Cochlear BAS (ref no. 90410, 90305, 90434, 90480).

4. **Intended Use**

The Ponto Pro Power sound processor is intended for improvement of hearing for patients with conductive and mixed losses, bilateral fitting and single sided deafness.

5. **Technological characteristics, comparison to predicate device**

Characteristics	Ponto Pro Power	Ponto Pro	BP100	Baha Intenso™	S/Eq
Design	Bone conduction sound processor connected to an implant which has been surgically placed in the bone behind the ear	Bone conduction sound processor connected to an implant which has been surgically placed in the bone behind the ear	Bone conduction sound processor connected to an implant which has been surgically placed in the bone behind the ear	Bone conduction sound processor connected to an implant which has been surgically placed in the bone behind the ear	Yes
Indications for use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness	Yes
Pure tone average bone conduction threshold of the indicated ear for patients with conductive or mixed hearing loss	Better than or equal to 55 dB HL (measured at 0.5, 1, 2, 3)	Better than or equal to 45 dB HL (measured at 0.5, 1, 2, 3 kHz)	Better than or equal to 45 dB HL (measured at 0.5, 1, 2, 3 kHz)	Better than or equal to 55 dB HL (measured at 0.5, 1, 2, 3)	Yes
Material	Sound processor coupling: PEEK	Sound processor coupling: PEEK	Sound processor coupling: PEEK	Sound processor coupling: PEEK	Yes
Power requirement	Zinc-air battery	Zinc-air battery	Zinc-air battery	Zinc-air battery	Yes
Max gain at 1600 Hz	47 dB	33	33	45 dB	Yes
Frequency response	125 Hz – 8 kHz	125 Hz – 8 kHz	250 Hz – 7 kHz	250 Hz – 7 kHz	Yes
Sound processing	Digital	Digital	Digital	Digital	Yes
Patient fitting	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist.	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist.	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist.	Individual adjustment to patient audiogram and needs by potentiometers adjusted by the audiologist using a screwdriver.	Yes
Manufacturer	Oticon Medical AB	Oticon Medical AB	Cochlear Bone Anchored Solutions AB	Cochlear Bone Anchored Solutions AB	Yes
K-number	No number yet	K090996 K082108	K090720	K081606	

6 Discussion of testing

Testing of the Ponto Pro Power has been performed to verify design criteria and device performance with respect to mechanical, electroacoustical and software properties.

Published data in the literature support the safety and efficacy of the predicate device, Baha Intenso for patients with average bone-conduction thresholds of< 55 dB HL. Bench performance data has verified the Ponto Pro Power to be equivalent to the predicate device in terms of device gain and maximum force output. Therefore Ponto Pro Power is considered to successfully fit the same patient population; i.e. those with bone-conduction thresholds of < 55 dB HL.

Verification of the safety and effectiveness of the new sound processing features introduced for Ponto Pro Power; Wind noise reduction, Dynamic Feedback Cancellation, Speech Guard and BC In-situ Audiometry include bench performance testing as well as clinical evaluation. Bench performance data of the wind noise reduction feature verify that when exposed to a preset air flow the device responds to the air flow/wind by reducing overall gain and switching mode, respectively. Bench performance data on the Dynamic Feedback Cancellation (DFC) feature show that feedback is identified and cancelled out by the DFC system without artifacts being introduced. Bench testing of the Speech guard feature include testing of the behavior of Speech Guard at different gain settings, input levels, and different types of noise input and shows that the device is able to maintain linear processing as much as possible, while at the same time responding instantaneously to rapidly occurring environmental sounds. The bench data confirms the effectiveness of the sound processing features and ensure that no negative effects are introduced.

Clinical data include comparisons with the predicate device Baha Intenso (K081606). In an unpublished study funded by the submitter, performance data of both instruments were collected from 20 experienced users of Intenso, 18 subjects had mixed hearing losses and 2 were single-sided deaf. Only results from the homogenous group of the 18 subjects with conductive and mixed hearing losses were analyzed. 5 subjects were male and 13 female. The age range between 17 years and 75 years, average age of the subjects was 58.1 years, SD 14.53 years. All subjects had used Baha Intenso for at least 4 months and were tested with the Intenso prior to testing with the Ponto Pro Power .
Performance of both devices was evaluated objectively in the clinic in terms of aided thresholds, speech perception in quiet and speech perception in noise. Abbreviated Profile of Hearing Aid Benefit (APHAB) and the Speech Spatial and Quality Scale of Hearing (SSQ). In addition, user experiences, user satisfaction, and device preference among subjects were probed via questionnaires.
The aided thresholds were essentially similar for both devices; no significant differences were observed between the two devices.

Ponto Pro Power was verified to be substantially equivalent to the predicate device Baha Intenso, both concerning subjective evaluation on wind noise and feedback and in terms of speech reception threshold in quiet and speech reception threshold in noise.

To verify the effect of BC In-situ Audiometry conventional unmasked BC hearing thresholds was measured with two methods for a group of 25 hearing impaired patients, an audiometer using a RadioEar B-71 bone conduction transducer and the BC In-situ Audiometry tool in Genie Medical via the sound processor on the patients abutment. The difference between both measurement methods is on average less than 5 dB. Taking audiometric step size (5 dB) and size of population into account, both measurement methods can be regarded as similarly sensitive for audiometric BC threshold measurements.

7 Conclusion

Based on the comparison to the predicate devices, the Oticon Medical Ponto Pro Power, is substantially equivalent to devices already on the market cleared by the 510(k) process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Oticon Medical AB
c/o Ms. Ulrika Nielson
Quality and Regulatory Manager
Ekonomiv. 2
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Sweden

JUN 15 2011

Re: K103594
Trade/Device Name: Ponto Pro Power
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: May 3, 2011
Received: May 6, 2011

Dear Ms. Nielson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. INDICATIONS FOR USE

510(k) Number: K103594

Device Name: Ponto Pro Power

Indications for Use:

The Ponto Pro Power 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 of the indicated ear should be better than or equal to 55 dB HL (measured at 0.5, 1, 2 and 3 kHz)
- 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 Pro Power sound processor is intended to be connected to the Oticon Medical bone anchored implant system or to the Baha® Abutment snap coupling from Cochlear Bone Anchored Solutions AB (ref no. 90410, 90305, 90434, 90480).

Prescription Use__X__ OR Over-The-Counter Use_____
(Part 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103594