

K090996

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

JUL 29 2009

Summary of Safety and Effectiveness

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

SUBMITTER'S NAME: Oticon Medical AB
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DATE OF SUBMISSION: April 6, 2009

1. Identification of device

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

2. Equivalent devices

Oticon Medical believes that the Ponto Pro, regarding intended use, function and procedure, is substantially equivalent to the OBC cleared in 510(k) K082108, has substantially equivalent fitting technology as air conduction hearing aids with digital sound processing (exempt from 510(k)) and has substantially equivalent accessories for direct audio input as the Baha® Divino cleared in 510(k) K042017.

3. Description of the Device

The Ponto Pro is a bone conduction-type hearing aid. The Ponto Pro sound processor 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. The Ponto Pro sound processor has a coupling so that it can be easily connected to and disconnected from the abutment by the user. The Ponto Pro can alternatively be connected to head band accessories, to function as a conventional bone conductor. Using a computer based fitting system the Ponto Pro can be adjusted to the patient's individual hearing requirements. 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). In addition, the Oticon Medical abutments can be used for connection of the Baha® sound processors with snap coupling from Cochlear BAS (Baha Divino®, Baha Intenso™, Baha Cordelle II, Baha BP100; ref no. 90500, 90510, 90501, 90511, 90502, 90512, 90503, 90513, 90730, 90731, 90732, 90733, HBC 400-0, HCB 401-0, HCB 402-0, 91300, 91301, 91302, 91303, 91304, 91305).

4. Intended use

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

5. Technological characteristics, comparison to predicate device

Comparison table

Characteristics	Ponto Pro	OBC	BAHA Divino	Air conduction Hearing Aids with digital sound processing	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	Air conduction sound processor placed behind the ear or in the ear canal.	Yes
Intended 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	Yes
Material	Sound processor coupling: PEEK Implant: Titanium	Sound processor coupling: PEEK Implant: Titanium	Sound processor coupling: PEEK Implant: Titanium	Multiple	Yes
Power requirement	Zinc-air battery	Zinc-air battery	Zinc-air battery	Zinc-air battery	Yes
Max gain	33dB	33dB	33dB	N/A	Yes
Frequency response	125 Hz – 8 kHz	125 Hz – 8 kHz	125 Hz – 8 kHz	N/A	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 at the manufacturer on request from the audiologist.	Individual adjustment to patient audiogram and needs by potentiometers adjusted by the audiologist using a screwdriver.	Individual adjustment to patient audiogram and needs by a computer based fitting system used by the audiologist	Yes
Accessories	Various accessories for direct audio input (DAI)	Various accessories for direct audio input (DAI)	Various accessories for direct audio input (DAI)	N/A	Yes
Manufacturer	Oticon Medical AB	Oticon Medical AB	Entific Medical Systems AB	N/A	
K-number	No number yet	K082108	K042017	Exempt from 510(k)	

6. Discussion of testing

Testing of the Ponto Pro include functional testing and software validation. These tests verify that the Ponto Pro is functionally equivalent to the OBC, why we have come to the conclusion that further testing will not raise new issues of safety and efficacy.

7. Conclusion

Based on the comparison to the predicate devices, the Oticon Medical Ponto Pro, is substantially equivalent to devices already on the market, both cleared by and exempt from the 510(k) process, and presents no new concerns about safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
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Oticon Medical AB
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Quality and Regulatory Affairs Manager
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SE-436 33 Askim
Sweden

JUL 29 2009

Re: K090996

Trade/Device Name: Ponto Pro Bone Anchored Sound Processor with Accessories
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: II
Product Code: LXB
Dated: July 10, 2009
Received: July 14, 2009

Dear Ms. Isberg:

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.

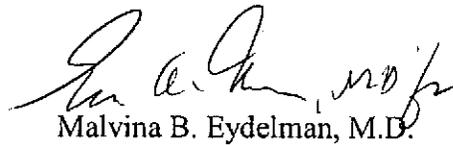
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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/cdrh/mdr/> 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

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

Enclosure

Indications for Use

510(k) Number (if known): K090996

Device Name: Ponto Pro

Indications For Use:

The Ponto Pro 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 for the indicated ear should be better than 45 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, who for some reason will not or cannot use an AC CROS. The pure tone average (PTA) air conduction (AC) threshold of the hearing ear should then be better than 20 dB HL (measured at 0.5, 1, 2 and 3 kHz).

The placement of a bone anchored implant is contraindicated for patients below the age of 5.

The Ponto Pro sound processor is intended to be connected to the Oticon Medical bone anchored implant system or to the Baha® Abutment snap coupling from Cochlear BAS. In addition, the Oticon Medical abutments can be used for connection of the Baha® sound processors with snap coupling from Cochlear BAS (Baha Divino®, Baha Intenso™, Baha Cordelle II, Baha BP100).

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

James R. Kane, Ph.D.
 (Division Sign-Off)
 Division of Ophthalmic, Neurological and Ear,
 Nose and Throat Devices

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