

SECTION 2. SUMMARY AND CERTIFICATION Nov 14 2008**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 OBC Bone anchored hearing aid system

SUBMITTER'S NAME: Oticon Medical AB
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DATE OF SUBMISSION: July 18, 2008

1. Identification of device

Proprietary Name: OBC Bone anchored hearing aid system
Common Name: Hearing Aid, Bone Conduction
Classification Status: Class II per regulations 21 CER § 874.3300
Product Codes: LXB

2. Equivalent devices

Oticon Medical believes that the OBC, regarding intended use, function and procedure, is substantially equivalent to BAHA Divino cleared in 510(k) K042017

3. Description of the Device

The OBC bone anchored hearing aid 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 has a coupling so that it can be easily connected to and disconnected from the abutment by the user. The sound processor can alternatively be connected to headband accessories, to function as a conventional bone conductor.

4. Intended use

The OBC 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	BAHA Divino	OBC	S/Eq
Design	Bone conduction sound processor connected to an implant which has been surgically placed in the bone behind the deaf ear	Bone conduction sound processor connected to an implant which has been surgically placed in the bone behind the deaf ear	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	Yes
Material	Implant: Titanium Sound processor coupling: PEEK	Implant: Titanium Sound processor coupling: PEEK	Yes
Power requirement	Zinc-air battery	Zinc-air battery	Yes
Max gain	33dB	33 dB	Yes
Frequency response	125 Hz – 8 kHz	125 HZ - 8kHz	Yes
Sound processing	Digital	Digital	Yes
Manufacturer	Entific Medical Systems, Inc.	Oticon Medical AB	
K-number	K042017	No number yet	

6. Discussion of testing

Laboratory testing of the OBC system was conducted to determine device functionality and conformance to design input requirements. These tests verify that the OBC is functionally equivalent to the to BAHA Divino from Entific Medical Systems, Inc., 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 device, the Oticon Medical OBC, is substantially equivalent to previously cleared predicate devices and presents no new concerns about safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Oticon Medical AB
c/o Ms. Karolin Isberg
QA/RA Manager
Ekonomiv. 2
SE-436 33 Askim
Sweden

NOV 14 2008

Re: K082108

Trade/Device Name: OBC Bone Anchored Hearing Aid System
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing Aid, Bone Conduction
Regulatory Class: Class II
Product Code: LXB
Dated: October 29, 2008
Received: October 31, 2008

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

K082108

B. INDICATIONS FOR USE

510(k) Number: _____

Device Name: OBC Bone Anchored Hearing Aid System

Indications for Use:

The OBC 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.

Prescription Use X OR Over-The-Counter Use _____
(Part 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K082108