JUN 2 8 1999

K984162

510(k) 984162

SUMMARY OF SAFETY AND EFFECTIVENESS

A. Name and Address

The Summary of Safety and Effectiveness is being submitted by Nobel Biocare USA, Inc., administrative office at 3944 N. Hampton Drive, Powell, Ohio, 43065. The telephone number is: 1-888-825-8484.

B. Name of Device

The device is generally known as a bone-anchored, bone-conduction hearing aid with the trade name "Branemark Bone-Anchored Hearing Aid (BAHA™) System. This submission is to allow the Branemark Bone-Anchored Hearing Aid to be used in patients from 5 years old and older.

C. The Predicate Product

The predicate product used in this Premarket Notification is the Branemark System® Bone-Anchored Craniofacial Prosthetic Attachment System (K945154), the Branemark Bone-Anchored Hearing Aid (K955713), the Audiant™ Bone-Conduction Hearing Aid (K861971, K872168 and K841432), and other bone-conduction hearing aids.

D. Description of Device

The Branemark Bone-Anchored Hearing Aid (BAHA) System includes a titanium fixture which is placed in the temporal bone just behind the ear, an abutment, various accessories necessary for the placement and use of the fixture/abutment pillar, and a sound processor which is attached to the abutment. The fixture/abutment pillar is used as an anchor for the sound processor.

SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

E. Indications for Use

This device is to be used by patients who have a conductive hearing loss and can still benefit from sound amplification. Also indicated are patients with mixed hearing loss with average bone conduction thresholds in the indicated ear better than 45 dB HL. (Patients with bone conduction thresholds between 25 and 45 dB HL will be expected to improve, but may not achieve levels in the normal range. Patients with a bone conduction threshold where each standard measured frequency threshold is less than 25 dB HL can be expected to have restored hearing levels in the normal range.) The patients indicated for this device must also be unable to use conventional air conduction hearing aids or undergo ossicular replacement surgery because of one of the following:

1. Chronic otitis media (COM); or

2. Congenital malformation (CM) of the middle/external ear; or

3. Other acquired malfunctions of the middle or external ear canals which preclude the wearing of a conventional air conduction hearing aid.

Additional indications to be met by perspective BAHA candidates:

1. Patients (either by themselves or with the aid of others) must be able to maintain the abutment/skin interface of the BAHA. Therefore, careful consideration must be given as to the patient's psychological, physical, emotional and developmental capabilities to maintain hygiene. In the case of children part, but not all, of that responsibility falls on the parents or guardian.

2. For children and patients with congenital malformations, sufficient bone volume and bone quality must be present for a successful fixture implantation. Alternative treatment such as conventional bone conduction hearing aids, should be considered for patients having a disease state that might jeopardize osseointegration.

SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

E. Indications for Use (continued)

Contraindications:

1. Speech discrimination scores of the indicted ear less the 60% at elevated sound pressure levels (SPL) during standardized tests.

2. Patients who are developmentally delayed or who suffer from drug abuse. (This includes children who have behavior problems or who have parents who are not able to keep the implanted area clean.

3. Age less than 5 years.

4. Patients who already have a BAHA (i.e. no bilateral implants). The BI-CROS attachment to the BAHA should be used for this purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 1999

Nobel Biocare
c/o Ms. Betsy A. Brown
B.A. Brown & Assoc.
Regulatory Specialists
8944 Tamaroa Terrace
Skokie, Illinois 60076

Re: K984162
Trade Name: Branemark Bone Anchored Hearing Aid (BAHA™) System
Regulatory Class: II
Product Code: 77 MAH
Dated: April 12, 1999
Received: April 15, 1999

Dear Ms. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984162- S1

Device Name: Branemark Bone-Anchored Hearing Aid (BAHA™) System for Pediatric Use

Indications For Use:

This device is to be used by patients who have a conductive hearing loss and can still benefit from sound amplification. Also indicated are patients with mixed hearing loss with average bone conduction thresholds in the indicated ear better than 45 dB HL. (Patients with bone conduction thresholds between 25 and 45 dB HL will be expected to improve, but may not achieve levels in the normal range. Patients with a bone conduction threshold where each standard measured frequency threshold is less than 25 dB HL can be expected to have restored hearing levels in the normal range.) The patients indicated for this device must also be unable to use conventional air conduction hearing aids or undergo ossicular replacement surgery because of one of the following:

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3. Other acquired malfunctions of the middle or external ear canals which preclude the wearing of a conventional air conduction hearing aid.

Additional indications to be met by perspective BAHA candidates:

1. Patients (either by themselves or with the aid of others) must be able to maintain the abutment/skin interface of the BAHA. Therefore, careful consideration must be given as to the patient's psychological, physical, emotional and developmental capabilities to maintain hygiene. In the case of children part, but not all, of that responsibility falls on the parents or guardian.

2. For children and patients with congenital malformations, sufficient bone volume and bone quality must be present for a successful fixture implantation. Alternative treatment such as conventional bone conduction hearing aids, should be considered for patients having a disease state that might jeopardize osseointegration.

(Please do not write below line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use**__
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K984162

(Optional Format I-2-96)

510(k) Number (if known): K984162-S1

Device Name: Branemark Bone Anchored Hearing Aid (BAHA™) System for Pediatric Use

Contraindications:

1. Speech discrimination scores of the indicated ear less the 60% at elevated sound pressure levels (SPL) during standardized tests.

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3. Age less than 5 years.

4. Patients who already have a BAHA (i.e. no bilateral implants.) The BI-CROS attachment to the BAHA should be used for this purpose.

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Prescription Use ✓ **OR** **Over-the-Counter Use** ___
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(Division Sign-Off)
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