Pre-market Notification

NOV 24 1999

K992872

Summary of Safety and Effectiveness

A. Name and Address

The Summary of Safety and Effectiveness is being submitted by Entific Medical Systems Inc.,3944 N. Hampton Drive, Powell, Ohio 43065 (formerly part of Nobel Biocare USA, 22895 East Park Drive, Yorba Linda California 92887). The contact person for this submission will be Betsy A. Brown, the regulatory specialist for Entific Medical Systems Inc. Ms. Brown can be reached at the following:

B.A. Brown & Asociates
8944 Tamaroa Terrace
Skokie, Illinois 60067
Tel# 847-677-8944
Fax# 847-677-0177

B. Name of Device

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

C. The Predicate Product

The predicate products used in this Premarket Notification are the Branemark Bone-Anchored Hearing Aid (BAHA™), K955713 and K984162, the Branemark System® Bone Anchored Craniofacial Prosthetic Attachment System, K945154 and other bone conduction hearing aids.

D. Description of the Device

The **Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II 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, a sound processor which is attached to the abutment and a body worn unit which has two potentiometers that control threshold knee and loundness boost and a tone control switch.

E. Intended Use of the Device

The **Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II System** is intended to be used as a bone-anchored, bone-conduction hearing aid. The device is indicated for use in patients who have 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 45dB HL. The nominal output from the BAHA Cordelle II is on average 13 dB stronger than the Classic 300 (measured at 0.5, 1,2,3 kHz). The Cordelle II is recommended for patients having the same indications for the Classic 300 but where the Classic 300 is "too weak". (Patients with bone conduction thresholds better than 45dB 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 psycholoigical, physical, emotional and developmental capabilities to maintain hygiene. In the case of children part, but not all, of that responsibility falls on the parent or guardian.

2. For children and patients with congenital malformation, 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.

Contraindications:

1. Speech discrimination scores of the indicated ear less than 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.

F. Comparison of Technological Characteristics

The technological characteristics between the attachment system, the sound processor and the respective predicate products are substantially identical and no additional questions regarding safety and effectiveness exist.

Substantial Equivalence

The **Branemark Bone-Anchored Hearing Aid (BAHA™) Cordelle II** is a sound processor system which consists of two units; a transducer and a body worn unit. The body worn unit has two potentiometers which control threshold knee and loudness boost and a tone control switch.

Transducer

The **transducer** is an at-the-ear level sound processor which uses a direct connection to the skull bone without intervening skin and soft tissue. The transducer is attached to a snap coupling titanium abutment, which is fastened to a titanium flange fixture using a gold screw. The transducer is connected to a body worn unit via a cord with electrical output and input connectors.

Body Worn Unit

As noted previously the **body worn unit** has two potentiometers which control the threshold knee and loudness boost. The unit is also equipped with an electrical input to receive signals from a "Walkman" FM/IR system. When the electrical contact is connected it overrides the telecoil signal.

Body Worn Unit (continued)

The body worn unit has a tone switch which controls the frequency response. The switch can be set in three different positions. N= Normal, which gives the widest frequency response. H= High frequency emphasis (reduction of low frequency sounds). L= Low frequency emphasis (reduction of high frequency sounds). The tone switch is effective for all inputs (microphone, telecoil, electrical).

The two trim controls marked LB and TK can be adjusted with a small screwdriver by the patient's audiologist. The LB adjusts the gain for loud sounds and the TK adjusts the gain for soft sounds.

The body worn unit is equipped with a clip so you can attach the unit to the patient's clothing (i.e. shirt/blouse pocket...).

Abutment Snap

There is an **abutment snap** which is mounted to the transducer. It is designed to snap into the abutment and hold the transducer securely in place.

Abutment Insert

The function of the **abutment insert** is to act as a guide for the abutment snap. It makes it easier to connect the transducer to the abutment. It also protects the inside of the abutment from dirt.

Abutment and Abutment Screw

The **abutment** is a replaceable percutaneous connection between the fixture and the external sound processor which is partially or totally submerged into soft tissue. The abutment is made of titanium and is fastened to the fixture via an internal an **abutment screw.**

Abutment Cover

When the transducer is not in place you can attach the **abutment cover** on the abutment to make it look more aesthetically pleasing. One can attach the cover by pressing it into place on the abutment.

Fixture

The **fixture** is a threaded titanium screw which is implanted into the temporal bone and intended to provide permanent bone anchorage as a means to attach the sound processor.

Cover Screw and Healing Cap

The **cover screw** and **healing cap** are temporary components utilized only during the healing periods post surgical placement of the titanium fixture. The cover screw is used during the first healing period and is attached to the fixture and covered with the soft tissue during the healing of the bone and soft tissue. The cover screw covers the upper part of the internal threads of the fixture. Thus, the cover screw will preclude bone and soft tissue from growing into the site where the abutment will be placed. The healing cap is used during the second healing period and covers the abutment surface. These components are used only during the healing stages of the surgery and remain in place for three to four months and one to two weeks respectively.

The **Branemark Bone-Anchored Hearing Aid BAHA®™Cordelle II System** is substantially equivalent to the Branemark Bone-Anchored Hearing Aid BAHA™, K955713, K984162 and to the Branemark System® Bone-Anchored Craniofacial Prosthetic Attachment System (BA-CPAS), K9445154 for the following:

1. The BAHA Cordelle II System has the same intended use as the predicate products

2. The BAHA Cordelle II System has the same identical technological characteristics as the predicate products

3. The BAHA Cordelle II System has the same identical surgical technique as the predicate products

4. The BAHA Cordelle II System has similar manufacturing processes; and same packaging and sterilization process as the predicate products

Therefore, based on the facts presented above, we believe the **BAHA™ Cordelle II System** is substantially equivalent to the predicate products and respectfully request the concurrence of the Agency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Ms. Betsy A. Brown
Regulatory Specialist for Entific Medical Systems
B. A. Brown & Associates
8944 Tamaroa Terrace
Skokie, IL 60076

Re: K992872
Trade Name: Branemark Bone-Anchored Hearing Aid (BAHA) Cordelle II
Regulatory Class: II
Product Code: 77LXB
Dated: July 28, 1999
Received: August 26, 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 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). 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,

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): # 992872

Device Name: Branemark Bone Anchored Hearing Aid (BAHA™) System Cordelle II System

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 45dB HL. The nominal output from the BAHA Cordelle II is on average 13 dB stronger than the Classic 300 model (measured at 0.5,1,2,3 kHz). The Cordelle is recommended for patients having the same indications for the Classic 300 but where slightly stronger amplification is needed than what is delivered by the Classic 300 model. (Patients with bone conduction thresholds better than 45dB 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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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.

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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 K992872

K992872

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