

AUG 30 2002

1021837

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

SUBMITTER'S NAME: Entific Medical Systems
ADDRESS: P:O: Box 16024
SE-412 21 Göteborg
Sweden
CONTACT PERSON: Constance Bundy
TELEPHONE NUMBER: 763-574-1976
FAX NUMBER: 763-574-2437
DATE OF SUBMISSION: June 1, 2002

1. Identification of device

Proprietary Name: Branemark Bone Anchored Hearing Aid
Common Name: BAHA™
Classification Status: Class II per regulations 21 CFR § 874.3300
Product Codes: LXB

2. Equivalent devices

Entific Medical Systems believes that the single sided deafness (SSD) indication for BAHA hearing aid is substantially equivalent regarding intended use to air conduction hearing aids with a CROS unit (exempt from 510(k)). The BAHA device and its fitting procedure is identical to the Branemark BAHA cleared in 510(k) 955713.

3. Description of the Device

The BAHA is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology.

The BAHA hearing aid is connected to a fixture pillar, which has been surgically placed in the bone behind the deaf ear. Sound is transmitted through the bones of the skull to the hearing ear with the normal functioning cochlea.

4. Intended use

BAHA hearing aid for SSD is intended for patients who suffer from unilateral sensorineural deafness.

BAHA hearing aid transmits the sound from the deaf side through the bones in the skull to the normal functioning cochlea and is intended to improve speech recognition.

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

Comparison table

Characteristic	BAHA for single sided deafness (SSD)	Air conduction Hearing Aids with CROS unit	BAHA – Branemark Bone Anchored Hearing aid	S/Eq
Material	Same as BAHA	Multiple	Implant: Titanium Abutment Snap: PEEK	Yes
Intended use	Improvement of hearing and speech recognition for SSD patients	Improvement of hearing and speech recognition for SSD patients	Improvement of hearing for patients with conductive and mixed hearing losses	Yes
Power requirement	Same as BAHA	N/A	Zinc-air	Yes
Max gain	Same as BAHA	N/A	33dB	Yes
Frequency response	Same as BAHA	N/A	125 Hz – 8 KHz	Yes
Manufacturer	Entific Medical Systems	N/A	Entific Medical Systems	
Classification code	LXB	ESD	LXB	
K-number	Pending	Exempt	K955713	

CROS = Contra-lateral Routing Of Signals

6. **Discussion of testing**


A clinical study was conducted to establish the benefits of BAHA for SSD including audiometric evaluation of speech perception in noise as well as a subjective questionnaire (APHAB).

7. **Conclusion**

It is the conclusion of Entific Medical Systems that the BAHA for SSD 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.

B. TRUTH AND ACCURACY CERTIFICATION, BAHA FOR SINGLE SIDED DEAFNESS

I certify that, in my capacity as Quality and Regulatory Manager, I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.



Quality and Regulatory Manager, Entific Medical Systems

May 24, 2002

Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 2002

Entific Medical Systems
c/o Constance Bundy
Regulatory Consultant to Entific Medical Systems
C.G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, MN 55432

Re: K021837

Trade/Device Name: BRÅNEMARK Bone-Anchored-Hearing Aid (BAHA™) for Single Sided Deafness (SSD)

Regulation Number: 874.3300

Regulation Name: Hearing Aid

Regulatory Class: Class II

Product Code: LXB

Dated: June 1, 2002

Received: June 4, 2002

Dear Ms. Bundy:

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

B. INDICATIONS FOR USE

510(k) Number K021837

Device Name: The BRÅNEMARK Bone-Anchored-Hearing Aid (BAHA™).

Indications for Use:

The use of BAHA hearing aid for SSD is intended to improve speech recognition.

The single sided deafness (SSD) indication for BAHA hearing aid is intended for patients who suffer from unilateral sensorineural deafness on one ear while the other ear has normal hearing. Normal hearing is defined as PTA AC threshold equal to or better than 20dB measured at 0.5, 1, 2 and 3 kHz.

BAHA for SSD is also indicated for patients who are indicated for an AC CROS but who for some reason cannot or will not use an AC CROS.

(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 Ear,
Nose and Throat Devices

510(k) Number K021837

Prescription Use OR Over the Counter Use _____
(Per 21 CFR 801.109)

Prescription Use _____
(Per 21 CFR 801.109)