K042017

AUG 2 6 2004

SECTION 0. 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:	July 26, 2004

1. Identification of device

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

2. Equivalent devices

Entific Medical Systems believes that the BAHA Divino has substantially equivalent technology as air conduction hearing aids with digital sound processing (exempt from 510(k)) and, regarding intended use, function and fitting procedure, is equivalent to previous models of BAHA cleared in 510(k) K955713, K984162, K011438 and K021837.

3. Description of the Device

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

The Divino 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

The BAHA Divino is intended for the following patients and indications:

- Patients who have a conductive or mixed hearing loss and can still benefit from sound amplification. The pure tone average bone conduction threshold should be better than or equal to 45 dB HL (measured at 0.5, 1, 2 and 3 kHz)

- Bilateral fitting of the Divino is intended for patients who suffer from moderate to severe bilateral symmetric conductive and/or mixed hearing losses. Symmetric bone conductive thresholds are defined as less than 10 dB in average (measured at 0.5, 1, 2 and 4 kHz) or less than 15 dB at individual frequencies

- The single sided deafness (SSD) indication for the Divino 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.

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

Comparison table

Characteristic	**BAHA –Branemark Bone Anchored Hearing aid**	**Air conduction Hearing Aids with digital sound processing**	**BAHA Divino**
Material	Implant: Titanium Abutment Snap: PEEK	Multiple	Same as BAHA
Intended use	Improvement of hearing for patients with conductive and mixed hearing losses, bilateral fitting and single sided deafness	Improvement of hearing	Same as BAHA
Power requirement	Zinc-air	N/A	Same as BAHA
Max gain	33dB	N/A	Same as BAHA
Frequency response	125 Hz – 8 KHz	N/A	Same as BAHA
Sound processing	Analogue	Digital	Digital
Manufacturer	Entific Medical Systems	N/A	Entific Medical Systems
K-number	K955713, K984162, K011438 and K021837	Exempt	Pending

6. **Discussion of testing**

Testing of the BAHA Divino included software validation and functional testing. These tests verify that the Divino is functionally equivalent to the BAHA.

7. **Conclusion**

It is the conclusion of Entific Medical Systems that the BAHA Divino with digital sound processing 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 2 6 2004

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

Re: K042017
Trade/Device Name: BAHA Divino®
Regulation Number: 21 CFR 874.3300
Regulation Name: Bone Conduction Hearing Aid
Regulatory Class: Class II
Product Code: LXB
Dated: July 26, 2004
Received: July 27, 2004

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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (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

Enclosure

B. INDICATIONS FOR USE

510(k) Number K042017

Device Name: BAHA Divino®

Indications for Use:
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(Please do not write below this 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 Ear,
Nose and Throat Devises

510(k) Number K042017