K024205

Premarket Notification [510(k)] Summary MAR 0 7 2003

SUBMITTED BY:
Everest Biomedical Instruments Co.
16690 Swingley Ridge Rd.
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Chesterfield, MO 63017
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CONTACT PERSON:
Randall J. Krohn

DATE OF PREPARATION
December 19, 2002

TRADE NAME:
AUDIOscreener OAE+ABR

COMMON NAME:
Otoacoustic Emissions Test Instrument / Evoked Response Auditory Stimulator

CLASSIFICATION NAME:
Audiometer (per 21 CFR section 874.1050) Panel 77 Product Code EWO

Evoked Response Auditory Stimulator (per 21 CFR section 882.1900) Panel 84 Product Code GWJ

PREDICATE DEVICES:
Kedly Audioscreener OAE+ABR (K001058)

DEVICE DESCRIPTION:
The Audioscreener OAE+ABR is a Otoacoustic Emissions and Audiotory Brainstem Response testing device to be used in the evaluation of hearing function. This device is essentially the Audioscreener OAE+ABR unit with additional software required to perform a Transient Evoked OAE in addition to the Distortion Product OAE test.

INTENDED USE:
The Audioscreener OAE+ABR may be used for patients of all ages, from newborn infants through adults. The Distortion Product Otoacoustic Emissions, Transient Evoked Otoacoustic Emissions, and Auditory Brainstem Response tests are indicated for use in screening individuals for hearing loss for whom behavioral audiometric responses are deemed to be unreliable, such as in infants, young children, and uncooperative or cognitively impaired adults.

TECHNOLOGICAL CHARACTERISTICS:
The Audioscreener OAE+ABR is similar in its intended use to predicate devices and existing methodologies. In addition, the device complies with the following safety and performance standards as applicable to its classification:

UL 2601-1 Medical Electrical Equipment Part 1: General Requirements for Safety 1st ed. 1997-10

CSA 22.2 No. 601.1 Medical Electrical Equipment Part 1: General Requirements for Safety-M90

IEC60601-1-2 Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests 1st ed. 1993-04

ANSI S3.6 Specification for Audiometers (sections 4-10 as applicable) 1996

IEC 60601-2-40 Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment (1998-02)

FDA Electroencephalograph Devices Guidance for 510(k) Content Draft Document Version 1.0 November 3, 1997

IEC 645-3 Audiometers Part 3: Auditory Test Signals of Short Duration for Audiometric and Neuro-Otological Purposes (1994-10)

IEC 60601-2-26 Particular Requirements for the Safety of Electroencephalographs (1994-04)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2003

Everest Biomedical Instruments Co.
c/o Randall J. Krohn
VP Engineering – Neuro Products
16690 Swingley Ridge Rd
Suite 140
Chesterfield, MO 63017

Re: K024205
Trade/Device Name: AUDIOscreener OAE+ABR
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: December 19, 2002
Received: December 20, 2002

Dear Mr. Krohn:

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

510(k) Number (if known): K024705

Device Name: Audioscreener OAE+ABR

Indications for Use:

The Audioscreener OAE+ABR may be used for patients of all ages, from newborn infants through adults. The Distortion Product Otoacoustic Emissions, Transient Evoked Otoacoustic Emissions, and Auditory Brainstem Response tests are indicated for use in screening individuals for hearing loss for whom behavioral audiometric responses are deemed to be unreliable, such as in infants, young children, and uncooperative or cognitively impaired adults.

(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 Devises

510(k) Number K024705

Prescription Use ✓
(Per 21 CFR 801.109)

(Optional Format 3-10-98)