K980533

ETYMOTIC RESEARCH

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MAR 23 1998

February 9, 1998

ERO•SCAN Otoacoustic Emissions Test Instrument

SUMMARY OF SAFETY AND EFFECTIVENESS

Classification Name:	Audiometer
Common/Usual Name:	Otoacoustic Emissions Test Instrument
Proprietary Name:	ERO•SCAN Otoacoustic Emissions Test Instrument
Establishment Registration:	1450042
Classification:	Panel 77, Procode EWO Classification 874.1050, Class II
Contact Person:	Steve Iseberg

The ERO•SCAN Otoacoustic Emissions Test Instrument is a hand-held device designed to provide an objective measure of outer hair cell function through the measurement of otoacoustic emissions (OAEs). This device is substantially equivalent to the marketed Etymotic Research Cub^{e}Dis Otoacoustic Emissions Test Instrument, 510(k) No. K930553, September 29, 1993.

Substantial equivalence of the ERO•SCAN instrument to Etymotic Research Cub^{e}Dis predicate device referenced above is based on the following:

- The intended use of the ERO•SCAN device and the predicate test instrument is to determine cochlear function by measuring distortion product otoacoustic emissions (DPOAEs) utilizing pure-tone stimulus presentation in adults, children and infants.

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- The ERO•SCAN device is manufactured and delivered completely assembled to the health care professional using materials and techniques widely used by other manufacturers of devices as with the predicate device.

- The ERO•SCAN instrument is battery powered, whereas the predicate device utilizes AC power to the DSP board and two 9-volt batteries for powering the preamplifier.

- Patient safety is preserved in both the ERO•SCAN and predicate devices. There is no direct electrical connection to the patient when using the ERO•SCAN unit. The predicate Cub^{e}Dis system, if used as intended, provides isolation with the plastic eartips so that there is no path for electrical conductance to the patient.

- The Ear Probe System ERO•SCAN components are similar to those incorporated in the predicate device, however the physical construction is not the same. The ERO•SCAN system has both receivers and microphone built into the screener. The probe assembly for the predicate Cub^{e}Dis system connects to an external preamplifier that connects to a PC computer-installed DSP board.

- Regarding hardware configurations, the DSP board hardware is housed inside a PC computer for the predicate device, whereas the ERO•SCAN DSP board is housed in a hand-held device.

- Software algorithms are essentially equivalent for both the ERO•SCAN and predicate devices.

- The parameters and principles of the signal processing are essentially the same in both systems with regard to stimulus duration, the use of signal averaging and Fourier transforms, and the f_1/f_2, fixed ratio of 1.2.

- The maximum sound level output of the ERO•SCAN Otoacoustic Emissions Test Instrument remains below +90 dB SPL throughout the audible frequency range of 20-20 kHz, which is equal to or less than that of the predicate device.

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The following comparison is provided as a summary of the technological characteristics relative to the ERO•SCAN Otoacoustic Emission Test Instrument and the predicate Etymotic Research Cub^{e}Dis Otoacoustic Emissions Test Instrument upon which the determination of substantial equivalence is based.

Characteristic	**Cub^{e}Dis System**	**ERO•SCAN Device**
Intended Use	Auditory test instrument designed to evoke or stimulate the generation of otoacoustic emissions for the purpose of determining the presence of cochlear function in adults, children and infants.	SAME
Hardware Design	DSP board hardware is housed in a PC computer. The probe assembly is connected to an external preamplifier that attaches to connections on the board.	DSP board housed in a hand-held device.
Software and Effectiveness	Software verification and validation is in accordance with FDA guidelines for computer controlled medical devices. QA procedures are adhered to and test results demonstrate that both system specifications and function requirements are met to perform DPOAE measurements.	SAME
Energy Source	AC power to DSP board with 9-volt battery power to preamplifier.	(4) 1.5v AA Batteries
Ear Probe System	External probe system housing 2 microphones and 2 speakers.	Microphone and receivers are integrated in the hand-held screener.
Performance Characteristics	Noise Floor: 0 dB SPL @ 1 kHz Frequency Range: 500 Hz – 8 kHz Stimulus Intensity Range: 40 – 70 dB SPL Maximum Output: ≤90 dB SPL	Noise Floor: 0 dB SPL @ 1 kHz Frequency Range: 2 kHz – 5 kHz Stimulus Intensity Range: 45 – 65 dB SPL Maximum Output: ≤90 dB SPL
Safety	The predicate Cub^{e}Dis system, if used as intended, provides electrical isolation with the plastic eartips so that there is no path for electrical conductance to the patient. Max. output <90 dB SPL.	No electrical connection to the patient. Max. output <90 dB SPL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1998

Krista M. Buckles, M.A., CCC-A, RAC
Consultant
Etymotic Research
61 Martin Lane
Elk Grove Village, Illinois 60007

Re: K980533
ERO-SCAN Otoacoustic Emissions Test Instrument
Dated: February 9, 1998
Received: February 11, 1998
Regulatory class: II
21 CFR 874.1050/Procode: 77 EWO

Dear Mr. Buckles:

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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): _____

DEVICE NAME: ERO•SCAN Otoacoustic Emissions Test Instrument

INDICATIONS FOR USE:

The ERO•SCAN Otoacoustic Emissions Test Instrument is a hand-held auditory test instrument designed to evoke or stimulate the generation of distortion product otoacoustic emissions (DPOAEs), utilizing pure-tone stimulus presentation, for the purpose of determining the presence of cochlear function in adults, children and infants.

Otoacoustic emissions are low-level audio-frequency sounds that are produced by the cochlea as part of the normal-hearing process. Available evidence suggests that otoacoustic emissions are generated by the cochlea's outer hair cells and that the presence of OAEs is an indication that the outer hair cells are viable. Clinical evidence indicates that these emissions normally occur with normal hearing or, at most, mild hearing loss (usually 30-40 dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980533