K070880

3.0 510(K) SUMMARY

Submission Date: March 30, 2007

Submitter Information:

JUN - 7 2007

Company Name: Etymotic Research, Inc.

Company Address: Etymotic Research, Inc.
61 Martin Lane
Elk Grove Village, IL 60007

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Manager of Instrumentation Products
Etymotic Research, Inc.
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Device Information:

Trade Name: ER35 ERO-SCAN Pro Hearing Test System

Common Name: ER35 ERO-SCAN Pro (ER35)

Classification Name: Audiometer and Auditory Impedance Tester

Device Class: Class II, 510(k) exempt, *21 CFR 874.1050*
Class II, *21 CFR 874.1090*

Predicate Devices: ERO-SCAN OAE Test System (K980533, K010165)
Etymotic Research, Inc.
Class II, 510(k) exempt

Interacoustics AT235 Impedance Audiometer (K994254)
International Distributors of Electronics for Medicine, Inc. (IDEM)
Class II

Device Description: The ER35 is a microprocessor-controlled instrument designed to screen otoacoustic emissions and tympanic membrane performance (tympanometry). Test information is stored in memory, displayed on a graphic LCD, and can be printed by a dot matrix printer or stored on a computer. The product is manufactured and delivered completely

assembled to the retailer using materials and techniques widely used by manufacturers of hearing devices

Intended Use: The ER35 is intended to be a test instrument that measures otoacoustic emissions and tympanic membrane performance (tympanometry).

Indications for Use: The ER35 ERO-SCAN Pro Hearing Test System (ER35) is indicated for testing of cochlear and middle ear function in infants, children, and adults by measuring otoacoustic emissions (OAEs) and tympanometry.

Comparison to Predicate Device:

All device parameters and patient contacting materials are the same for both the product which is the subject of this 510(k) and the predicate devices. In a few areas, the ER35 has reduced parameter ranges than the predicate devices.

Conclusion: The ER35 utilizes the same technology and has the same intended use as the cited predicate devices, and is therefore substantially equivalent (*21 CFR 807.92(a)(3)*).

Performance Standards: The ER35 is in compliance with the following performance and safety standards: *Specifications for Instruments to Measure Aural Impedance and Admittance (Aural Acoustic Immittance)* (ANSI S3.39-1987), American National Standards Institute, New York, 1996.; *Instruments for the Measurement of Aural Acoustic Impedance / Admittance* (IEC 60645-5), International Electrotechnical Commission, Geneva, 2004; and *Specification for Audiometers* (Dental/ENT) (ANSI S3.6-2004), American National Standards Institute, New York, 2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Etymotic Research, Inc.
c/o Campbell L. Tuskey
Becker & Associates Consulting, Inc.
2001 Pennsylvania Avenue NW, Suite 950
Washington, DC 20006

JUN - 7 2007

Re: K070880
Trade/Device Name: ER35 ERO-SCAN Pro Hearing Test System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, ETY
Dated: May 18, 2007
Received: May 21, 2007

Dear Ms. Tuskey:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

MB Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070880

2.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K 070880

Device Name: ER35 ERO-SCAN Pro Hearing Test System

Indications for Use:

The ER35 ERO-SCAN Pro Hearing Test System (ER35) is indicated for testing of cochlear and middle ear function in infants, children, and adults by measuring otoacoustic emissions (OAEs) and tympanometry.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of ... Devices
Nose and ...
510(k) Number K070880

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Prescription Use X
(Per 21 CFR 801.109)