DEC 16 2011 K112733

3.0 510(K) SUMMARY

Date Prepared: December 5, 2011

Submitter Information:

Company Name: 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 Otoacoustic Test Instrument (K980533; K010165)
Etymotic Research, Inc.

GSI 2000 (TympStar™) Middle Ear Analyzer (K000097)
VIASYS Healthcare (formerly Grason-Stadler Inc.)

Interacoustics AT235H Impedance Audiometer (K994254)
Interacoustics A/S

Device Description: The ER35 is a microprocessor-controlled instrument designed to screen otoacoustic emissions, tympanic membrane performance, and acoustic reflex. Test information is stored in memory, displayed on a graphic LCD, and can be printed by a 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, tympanic membrane performance (tympanometry), and acoustic reflex.

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

Comparison to Predicate Device:

All device parameters are similar for the product which is the subject of this 510(k) and the predicate devices. The intended use (including patient population) for the ER35 is consistent with those of the cited predicate devices.

Technological characteristics (i.e., design, material, and energy source) are identical to the ERO•SCAN Otoacoustic Test Instrument (K980533; K010165). The device is powered by 4 AA Alkaline cells, storing data (test records) via internal flash memory. The added functionality beyond OAEs does not affect the overall technological function and operation, compared to the predicate devices.

Certain performance specifications may vary compared to predicate devices, but in these cases, sufficient performance testing has been done to support substantial equivalence determination.

Performance testing: Non-clinical and clinical validation was performed in accordance with recognized consensus standards for this type of device. The ER35 has been demonstrated to be in compliance with the following performance and safety standards:

- *Specifications for Instruments to Measure Aural Impedance and Admittance (Aural Acoustic Emissions)* (ANSI S3.39-1987 (R2007)), American National Standards Institute, New York, 1996;

- *Medical Electrical Equipment, Part 1: General Requirements for Safety* (IEC 60601-1:2000), International Electrotechnical Commission, Geneva, 2000; and
- *Specification for Audiometers* (Dental/ENT) (ANSI S3.6-2004), American National Standards Institute, New York, 2004.

The ER35 is also in compliance with the following voluntary performance and safety standards: *Instruments for the Measurement of Aural Acoustic Impedance / Admittance* (IEC 60645-5:2004), International Electrotechnical Commission, Geneva, 2004.

Subjects tested included both male and female participants, an appropriate age range, and variable audiometric profiles (i.e., subjects with normal range hearing and impaired hearing function). No adverse effects or complications occurred. Performance data collected supports a substantial equivalence determination.

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)).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Etymotic Research, Inc.
c/o Mr. Jack Kent
Becker & Associates Consulting, Inc.
2001 Pennsylvania Avenue NW, Suite 950
Washington, DC 20006

DEC 16 2011

Re: K112733
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: September 20, 2011
Received: September 20, 2011

Dear Mr. Kent:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

K112733

2.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K112733

Device Name: ER35 ERO•SCAN Pro Hearing Test System

Indications for Use:

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

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)

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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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