DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 26, 2015

Etymotic Research, Inc.
% Ms. Meaghan Bailey
Senior Director, Medical Devices
NSF Health Sciences Medical Devices
2001 Pennsylvania Ave. NW, Suite 950
Washington, DC 20006

Re: K150491
Trade/Device Name: Er36 Series Oae Test System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: February 25, 2015
Received: February 25, 2015

Dear Ms. Bailey:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Deborah L. Falls -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150491

Device Name
ER36 Series OAE Test System

Indications for Use *(Describe)*
The ER36 Series OAE Test System is indicated for testing of cochlear function in infants, children, and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks or tones that are directed into the ear canal. 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 OAE's 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 30-40dB HL). The majority of hearing-impaired individuals will be identified by a simple OAE test.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY
ER36 Series OAE Test System

I. SUBMITTER

Company Name: Etymotic Research, Inc.
61 Martin Lane
Elk Grove Village, IL 60007
Tel: (847) 228-0006
Fax: (847) 228-6836

Contact Person: Meaghan Bailey, Senior Director, NSF Health Sciences

Date Prepared: February 25, 2015

II. DEVICE

Trade Name: ER36 Series OAE Test System
Common Name: Audiometer, Otoacoustic Emissions Device

Classification Name: Class II Audiometer
Device Classification: Class II, 21 CFR 874.1050

III. PREDICATE DEVICE

Predicate Devices: ERO•SCAN™ OAE Test System (K010165)
Etymotic Research, Inc.
Class II, 21 CFR 874.1050

Purpose of the Special 510(k) Premarket Notification: The ER36 is a modification of its predicate device.

IV. DEVICE DESCRIPTION

Device Description: The ER36 Series OAE Test System is a battery powered, hand-held microprocessor-controlled instrument designed to measure otoacoustic emissions. The ER36 is connected by a 1 meter, thin flexible cable to the ER36 MicroProbe OAE Test Probe (Ear Probe). The Ear Probe incorporates a field replaceable Probe Tip (9-lumen tube) that is inserted and acoustically sealed to the test ear canal with a compliant ear tip. The ER36 provides otoacoustic emissions measurements by two methods: distortion product otoacoustic emissions (DPOAE), and transient-evoked otoacoustic emissions (TEOAE). The OAEs are generated by a series of clicks or tones that are directed into the ear canal. Otoacoustic emissions are low level audio-frequency sounds that are produced by the cochlea as part of the normal hearing process.

Modifications and enhancements from the prior device version (ER34) includes updated electronic components removal of the device internal probe, change in ergonomics and the patient/user interface (i.e., LED/LCD display, ear probe housing material, and switch change), change in the dimensions of the controller housing, battery power change (Lithium-Ion rechargeable single cell), addition of a Bluetooth wireless printing option, and addition of a USB computer connection.

V. INDICATIONS FOR USE

Intended Use: The ER36 is a test instrument that measures otoacoustic emissions in infants, children, and adults.

Indications for Use: The ER36 Series is indicated for testing of cochlear function in infants, children and adults by measuring otoacoustic emissions (OAEs). The OAEs are generated by a series of clicks that are directed into the ear canal.

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The product has the same intended use, indications for use, and principle of operation as the ERO•SCANTM OAE Test System (K010165). Modifications to the device do not raise new or different questions of safety or effectiveness for the device's intended use. The results of risk analysis and design verification and validation activities provide evidence that the device is as safe and effective as its predicate. This evidence therefore demonstrates that the ER36 is substantially equivalent to its predicate device, ERO•SCANTM OAE Test System.

VII. PERFORMANCE DATA

The risk analysis method used to assess the impact of the modifications was ISO 14971:2007. According to the results of the risk analysis, the residual risks of the device were deemed acceptable in relation to device benefits. Design verification activities were performed to ensure the modified device was substantially equivalent to the predicate device and that it met performance specifications; this testing was performed on the basis of the risk analysis and per device design controls.

Conclusion: The ER36 utilizes the same technology and has the same indications for use as the cited predicate device (21 CFR 807.92(a)(3)), and is therefore substantially equivalent.