K131141

510K Summary

JUN 27 2013

Date:	April 18th, 2013
Submitted by:	PATH medical GmbH Landsberger Str. 63 82110 Germering Germany
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Contact person	Johann Oswald Director oswald@pathme.de
Name of device	Earprobe EP-TE and EP-DP
Common name	Evoked Response Auditory Stimulator
Classification name	Accessory to Evoked Response Auditory Stimulator (per 21 CFR section 882.1900) and otoacoustic emissions instruments
Predicative Device	Probe only of Echo-Screen T series (510 (k)# K013977)

Description of the Device

The Earprobes EP-DP and EP-TE are passive Transducers, which are used to covert electrical stimulus into acoustical stimulus. The electrical stimuli are provided by otoacoustic emissions devices or auditory evoked responses stimulators (afterwards referred as interfacing instruments). The acoustical stimulus is then coupled into the patient's ear.
The probe comprises of four sections:
a) Electrical transmission path
b) speaker and microphone
c) acoustic transmission path
d) transducer case

a) The electrical transmission path is connected to the interfacing instrument by a connector, which is connected to a shielded cable. The other end of the cable is attached to the microphone and speaker system.
Within the connector, an EEPROM is placed to store calibration data of the probe and to enable an interfacing device to identify the attached probe.

b) Each of the two speakers (in case of EP-DP) or the only speaker (in case of EP-TE) converts the electrical stimulus into an acoustic stimulus. The acoustic stimulus is delivered to the patient's ear by means of the acoustic transmission path.
One microphone in the probe is used to pick up the acoustical stimulus (which is delivered by the acoustical transmission path) and convert it to an electrical stimulus.

c) The acoustic transmission path is separated for each speaker and microphone. It consists of a silicone sealing which contains the speaker and microphones and connects to the acoustic ducts, which are implemented within the probe tip. The ducts are separated from each other and are used to smooth the acoustic output at the probe tip. Ear tips, which is not part of the probe, are put onto the tip of the probe tip in order to interface to the patient's ear.

d) The transducer case is the housing of the speaker and microphone and acts as the bridge between electrical and acoustical transmission path. It also provides means of handling.

Intended use of the Device
The Ear Probe is intended to be an accessory to auditory testing equipment that use evoked responses (e.g. DPOAE, ABR) to assess hearing function.

- The Ear Probe is capable of both generating and recording sounds in the ear canal.
- The Ear Probe is intended for use in all ages.

The interface to the patient's ear is provided by means of disposable standard eartips, which are available as separate consumables.

Comparison to Predicative Device:

The Earprobe EP-DP and EP-TE (from now on referred to as EP) were designed as accessories for different otoacoustic emissions instruments and auditory response stimulators. In comparison to the probe of the Echo-Screen T series (510 (k)# K013977), the Earprobe EP share the same technological characteristics.

The Earprobe EP and Echo-Screen probe comprise of a cable with connector on one end and probe on the other end. The only difference is the cable manufacturer, cable color and dimensions and connector type.
In both probes, within the connector, an EEPROM is placed to store calibration data of the probe and to enable an interfacing device to identify the attached probe

The microphone and the loudspeaker in the Earprobe EP and Echo-Screen probe are housed in a transducer case. The manufacturer of the loudspeaker and microphones are the same. Only the type of the speakers are different together with the physical dimensions, color and shape of the housing.

Similar to the Echo-Screen probe, the Earprobe EP has a removable probetip with separate ducts to deliver the acoustical stimuli and pick up the acoustical response. The only difference is the shape, dimension and color.

The intended use of both the Earprobe EP and the Echo-Screen probe is the same.
Both are intended to be used as transducers to convert electrical stimuli delivered by an otoacoustic emissions instrument or evoked response stimulator, into acoustical stimuli, which is then delivered to the patient's ear.

In both cases, the Earporbe EP and the Echo-Screen probe, a disposable eartip will be used to interface to the patients ear. The eartips to be used with the Earprobe EP are standard eartips and not part of this 510 (k).

Substantial Equivalence Performance Metrics
Substantial equivalence to the probe of the EchoScreen is based on non clinical performance testing of the acoustical and electrical parameters.

The Earprobe EP DP and EP-TE are already certified with CE mark together with the Sentiero device (from PATH medical for preschooler's hearing screening). To reach certification for the instrument together with the Earprobe EP, the following performance studies were conducted:

- ☒ Earprobe EP connected to AccuScreen (equivalent to EchoScreen TDA, GN Otometrics, Danmark). This study was conducted in comparison to the orignial AccuScreen probe connected to AccuScreen and is a proof of substantial equivalence in performance.
- ☒ Earprobe EP connected to Otobox (a clinical research platform of Technische Universitaet Muenchen, Munich, Germany.)
- ☒ Earprobe EP connected to Sentiero (PreSchool Hearing Screening Instrument using TEOAE and DPOAE, PATH medical GmbH, Germany)

Performance and safety testing was conducted in different hospitals in Germany and Danmark. As the probe itself is passive, the firmware of the active instrument to which the probe connects to and the used eartips are crucial components for performance testing and substantial equivalence.

In this 510 (k) application, the probe without instrument and without eartips shall be compared to the substantial equivalent probe of echo-screen with respect to the electrical interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 27, 2013

PATH medical GmbH
Dr. Johann Oswald
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Germering, Bavaria 82110
GERMANY

Re: K131141
Trade/Device Name: Earprobe EP-DP and EP-TE
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: May 21, 2013
Received: May 21, 2013

Dear Dr. Oswald:

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 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. 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,

Eric A. Mann -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

Indications for Use

510(k) Number (if known): K131141

Device Name: Ear Probe EP-DP and EP – TE

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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)

Eric A. Mann -S
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