DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 9, 2014

PATH Medical GmbH
c/o Dr. Johann Oswald
Director of PATH Medical GmbH
Landsberger Str.63
Germering, Bavaria
GM D-82110

Re: K133012
Trade/Device Name: Sentiero
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ, ETY
Dated: May 1, 2014
Received: May 6, 2014

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 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,

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

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)*

Device Name
Sentiero

Indications for Use *(Describe)*

Sentiero is a portable instrument to diagnose all ages for hearing loss. The instrument offers different test methods which can be configured to fit the professional's needs for screening or diagnostic purposes. It offers physiological test methods such as:

- Distortion Product Otoacoustic Emissions (DPOAE)
- Transient Evoked Otoacoustic Emissions (TEOAE)
- Auditory Brainstem Response (ABR)
- Auditory Steady State Response (ASSR)
- Auditory Impedance and acoustic reflex (TYMP) Additionally if offers standard audiometry (psycho-acoustical).

All physiological test methods are especially indicated for use in defining the type and configuration of hearing loss particularly for individuals whose behavioral audiometric results are deemed unreliable or to assist in the diagnosis of otologic disorders. Estimation of cochlear hearing thresholds (DP THRESH) is possible at various frequencies without the need of cooperative interaction with the patient. Acoustic reflex and tympanometry (TYMP) are featured to evaluate the functional condition of the middle and outer ear. For each method, several protocols can be configured. The results are to be used to make further recommendations regarding appropriate intervention strategies. Therefore, Sentiero is intended for use by trained personnel such as audiologists, pediatricians, ENT doctors and other health care professionals. In the United States of America, Federal law restricts this device to sale by or on the order of a licensed physician.

Available psycho-acoustical methods on Sentiero are especially indicated for use with cooperative patients starting at the age of 2 years or adequate development age, which enables them to do play/interactive audiometry. All other modules are suitable to be used for all ages.

Sentiero is designed for:

1. Diagnostics, monitoring and follow-up after newborn hearing screening
2. Pre-school, school, and adult hearing screening
3. ENT diagnostics based on measurement of
   - Otoacoustic emissions
   - Tympanometry and acoustic reflex
   - Auditory Brainstem Responses
   - Auditory Steady State Responses

Sentiero must not be used in cases of external otitis (outer ear canal infection) or in any case which yields to pain when inserting the ear probe or applying any other transducer.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Shuchen Peng -S

Shuchen Peng -S
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