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K133012

510(k) Summary

SUBMISSION INFORMATION

Date of preparation:	May 4th, 2014
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DEVICE INFORMATION

Device Name:	Sentiero
Device Trade Names:	Sentiero Basic, Sentiero Advanced, Sentiero Desktop
Device Identification Codes:	SOH100098, SOH100360, SOD100497
Common Name:	Evoked Response Auditory Stimulator
Classification Name:	Evoked Response Auditory Stimulator, Audiometer, Auditory Impedance Tester FDA 21 CFR section 882.1900 and 874.1050 and 874.1090

PREDICATE DEVICES

Cochlea-Scan	510(k) number: K061744
AccuScreen	510(k) number: K122067
Chartr EP 200	510(k) number: K092373
TITAN IMP440	510(k) number: K083861
Eclipse	510(k) number: K070696

DEVICE DESCRIPTION

Sentiero is an audiometric examination platform which consists of the Sentiero device with a touch screen display together with different accessories such as mains adapter, OAE probes, headphones, bone conductor, electrode cable, ear coupler cable, patient response switch. All connectors and transducers have a special plug in order to ensure the correct connection to the device. All plugs of the transducers have a memory chip inside which stores the information about the respective transducer (including type of

connector, calibration table). As a result, the Sentiero instrument can be connected flexibly to different kind of transducers while enabling the instrument to 'know' the features of the connected transducer. This information is used within the different modules (test methods which are configured) to guide the user (feedback via display) and help to ensure correct performance of the test methods.

Sentiero is available in two different models: handheld or desktop version. The desktop version is labeled Sentiero (Type Desktop). Both versions are standalone examination platforms and can be connected to a personal computer (PC) via USB for data review and management. The handheld version is portable and is meant to be mainly used as mobile device. The desktop version is portable as well but is meant to be mainly used as stationary device. Both models base on a common hardware platform (printed circuit board, PCB) but with different configurations. Materials in contact with humans are selected to be biocompatible.

Furthermore, each model can be configured to allow different test methods and features (modules) by a license key in the device. Sentiero is based on configurable modules. Sentiero can have one single module or a combination of multiple of modules described in the following intended use.

The measurement application is controlled from a self-contained firmware (software installed on the instrument). The measurement flow is menu guided on a touch screen. Evaluation of test results is based on signal statistics (if available for the test method). Besides that wave forms and result information is displayed for the user's evaluation.

See also "Indications for Use".

The following accessories are available to conduct the different measurement modules:

- TEOAE probe: PATH EP-TE
    - Clearance by FDA following the submission of a 510(k) K100661 and update on K131141
- DPOAE probe: PATH EP-DP
    - Clearance by FDA following the submission of a 510(k) K100661 and update on K131141
    - In combination with a silicon tube attached to Sentiero SOD and Earprobe EP-EP, the probe can be used as stimulator for the TYMP module.
- Electrode cable: PATH
    - shielded, passive cable to connect the instrument to electrodes for ABR or ASSR
- Headphones: Sennheiser HDA 280, Sennheiser HDA 200, Interacoustics DD 45, Holmco PD 81, GN Otometrics otoInsert, PATH Ear Coupler Cable
    - Only certified standard audiometry headphones are used in conjunction with Sentiero.
- Bone conductor: RadioEar B71
    - As stated by RadioEar (FDA establishment registration number 2516347): "The Bone Conductor does not come under the FDA Regulations for Medical Devices nor the FDA 510(k) Pre-market Approval provisions."
- Patient response switch
    - Passive switch for the patient to feedback his response to pure tone audiometry (heard or not heard equals pressed or not pressed as indicated in standard ISO 8253-1)

These accessories can be connected to Sentiero based on a special plug, which holds the information about the connected transducer / cable. Therefore the firmware can make use of this information and adapt the measurement procedures accordingly or provide information to the user via its display.

INTENDED USE

Sentiero is a portable instrument to diagnose all ages or 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 (DPTHRESH) 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 a medical or home environment. 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 elder than.infants from 34 weeks (gestational age) that are ready for discharge from the hospital.

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

a) Otoacoustic emissions

b) Tympanometry and acoustic reflex

c) Auditory Brainstem Responses

d) 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.

COMPARISON TO PREDICATE DEVICES

In terms of technology, workflow, and accessories, the predicate device **AccuScreen** shares most of the characteristics of Sentiero. In contrast to AccuScreen, which is a screening device, Sentiero provides diagnostic features based on sophisticated algorithms.

With respect to the intended use, combining psycho-acoustical and physiological test modules in a single handheld device, the **Cochlea-Scan** is similar.

With respect to diagnostic features on evoked potentials, **Chartr EP 200** (ABR and ASSR) and **Eclipse** (OAE, ABR, and ASSR) can be seen as predicate devices.

With respect to the auditory impedance and acoustic reflex testings (TYMP), the **Titan IMP440** can be seen as predicate device.

In order to facilitate the comparison, first the device setup and technical features and then the modules' features are compared.

1) Device setup and technical features (including accessories)

Design and working principles of Sentiero are very similar to Cochlea-Scan as well as AccuScreen. The similarity can be attributed to the fact that the same engineers at Fischer-Zoth Diagnosesysteme GmbH (Germany), who designed the Cochlea-Scan at that time, also designed the Sentiero as well as the AccuScreen at PATH medical GmbH. Accessories like probe and cables were designed and are used for both AccuScreen and Sentiero identically. These two systems were also designed in the same period of time using the same technology standards. In contrast thereto, Cochlea-Scan uses older technology standards. Therefore, the comparison to the predicate device with respect to technological characteristics is focused on the comparison between AccuScreen and Sentiero. Non-clinical performance data are also considered substantially equivalent: the development process was conducted by the same engineers and the resulting devices were tested to be compliant to the same standards by independent laboratories.

Both systems, Sentiero and AccuScreen, are battery driven handheld devices with the user interface on a 3.5" touch screen (Sentiero type MOD 100497: 5.0"). Probes and electrode cables are connected to the devices with similar plugs. Probes, electrode cables, ear coupler cable and interface cable to the PC (USB) are identical.

Sentiero and AccuScreen provide the same measurement methods (DPOAE, TEOAE and ABR) in order to provide statistically sound results. In contrary to the AccuScreen, which provides a pass/refer result as an automated screening result, the signal processing information is used in Sentiero only as an indicator (traffic light or indicator for valid response). In addition, wave forms (ABR) or frequency domain information (TEOAE and DPOAE) are provided together with additional diagnostic information and environmental information of the measurement to inform the user about the quality of the measurement.

The primary mechanical difference between AccuScreen and Sentiero is the housing which contains the printed circuit board (PCB) and the charging of the built-in rechargeable batteries. AccuScreen can be connected to a docking station for charging and data transfer. In contrast thereto, Sentiero must be connected to a custom made plug for connecting to the charger. Data transfer is possible via a USB cable connected directly to the device. Both housings are made of biocompatible material to fulfill the standards accordingly.

Both devices, Sentiero and AccuScreen, show similar performance data and compliance to the following standards:

- IEC **60601-1:2005**
- IEC **60601-1-2:2007**
- IEC **60601-1-4:1996**
- IEC **62304:2006**
- ISO **10993-1:2009**

Safety Electromagnetic compatibility Programmable electrical systems Software lifecycle Biocompatibility

In conclusion, Sentiero is substantially equivalent to the predicate device AccuScreen with respect to technological characteristics and non-clinical performance data.

2) Device measurement features

From a measurement perspective, the methods of predicting a behavioral threshold by means of DPOAE are similar to the predicate device Cochlear-Scan. Also the feature to combine psycho-acoustical test methods like pure tone audiometry and TEOAE or DPOAE on a diagnostic level is similar between both devices. Again, this is supported by the fact, that the same engineers developed both devices. In comparison to Cochlea-Scan, the most significant difference is the technological improvements added to the design of Sentiero. Nevertheless, substantial equivalence is given with respect to the diagnostic features of OAE measurements and hearing threshold predictions.

Additional diagnostic features and measurement techniques were added to Sentiero in comparison to AccuScreen or Cochlea-Scan, which are similar to Chartr EP 200 and Eclipse. Namely the ABR and ASSR features of Sentiero are similar to these predicate devices.

Sentiero uses up to two channels of data recording to run several diagnostic protocols and modalities. The firmware can be configured to run ABR with a traditional click stimulus but also with a tone burst stimulus to predict frequency specific behavioral hearing thresholds. This is similar to the predicate devices Chartr EP 200 and Eclipse. Besides that, Eclipse also provides similar run-time compensated stimuli – similar as Sentiero does (time-delay compensation of the traveling wave on the basilar membrane).

Sentiero can conduct ASSR with a 40 or 80 Hz repetition rate. Several stimuli can be combined together simultaneously and also on both ears to assess responses to various frequencies at the same time. The evoked response spectrum can yield the information about the presence or absence of the response to stimuli so that ASSR thresholds are supposed to hold a predictable relationship to behavioral thresholds that is dependent on stimulus frequency and the presence or degree of hearing loss. This is similar to the predicate devices Chartr EP 200 and Eclipse.

Besides the difference of dimensions, another difference is that Sentiero can do ABR or ASSR measurements as a standalone system and is therefore not dependent on a PC during the measurement. Chartr EP 200 and Eclipse are all PC-controlled devices.

In a first clinical evaluation in 2011, Sentiero and the predicate device Chartr EP 200 have been tested on the same test persons by different users (trained technicians in audiology). Morphology and latencies of

wave V have been analyzed. Furthermore, the usage of the device was evaluated by the feedback of the users. All results have been evaluated by an expert in audiology. Both systems, Sentiero and Chartr EP 200, were described as reliable clinical ABR devices, which supports the substantial equivalence between both instruments with respect to clinical performance. The run time compensated stimuli and algorithms are similar between Sentiero and Eclipse as they were taken out of the descriptions in published literature.

Sentiero also complies to the relevant standards 60645-1, 60645-6 and 60645-7 which displays that TEOAE, DPOAE and evoked potentials can be recorded as safe and as effective as the predicate devices.

Sentiero (Type MOD 100497) can also be configured to allow measurements of auditory impedance and acoustic reflex, which are also present on the predicate device TITAN IMP 440. The other types of Sentiero cannot be configured to use the TYMP module. The stimulus is transmitted via the EarProbe EP-DP in conjunction with a silicon tube in parallel to the probe to deliver the air pressure, which is produced by a pump inside the housing of Sentiero. The TYMP is conform to a IEC 60645-5 / ANSI S3.39 Type 1 acoustic impedance instrument.

In order to facilitate the comparison, the device setup and technical features are compared in *the following table* to the respective predicate device.

Parameter for Comparison	**Cochlea-Scan**	**AccuScreen**	**Chartr EP 200**	**Eclipse**
Intended Use	Same: Hearing screening and diagnostics by means of OAE and pure tone audiometry.	Same: Hearing screening with statistical evaluation of results by means of OAE and ABR. Different: Limited purpose (screening) and age group (newborns).	Same: Hearing diagnostics with ABR and ASSR. Different: No screening, no OAE tests for specific examination of inner ear hearing status.	Same: Hearing diagnostics and neurological screening with OAE, ABR, and ASSR.
Patient Population	Same: All ages	Different: Newborns only	Same: All ages	Same: All ages
Device Hardware Setup	Same: Standalone, handheld / portable device, battery-powered.	Same: Same touch screen display with same resolution, connectors to cables and transducers. Different: Housing, docking station	Different: Connected to PC, not standalone.	Different: Connected to PC, not standalone.
Ear Probe	Same: See K131141.	Same: Same probe, special plugs		

Parameter for Comparison	Cochlea-Scan	AccuScreen	Chartr EP 200	Eclipse
		including memory.		
Electrode Cable	Same:	Same: Same cable, special plugs including memory.		
Headphones, Insert Earphones	Same: Additional headphones or inserts available – automatic detection through memory in plug	Different: No headphone or insert earphone to be connected.		
Safety, Characteristics, Performance	**Same:** IEC 10993-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, EN 1041, ISO 980 (ISO 15223- 1), IEC 60645-1,	**Same:** IEC 10993-1, IEC 60601-1, IEC 60601-2, 60601-1-4, IEC 60645-6, IEC 606045-7, IEC 62304, IEC 62366 (IEC 60601-1-6)	**Same:** IEC 60601-1-2, IEC 60601-2-40 **Different:** No encephalography application is mentioned for the predicate device. Nevertheless, the predicate device is compliant with IEC 60601-2-26. Sentiero does not comply with EN 60601-2-26 as intended use is not for cerebral monitoring or electro-encephalography.	**Same:** IEC 60601-1, IEC 60601-2, IEC 60645-1, **Different:** IEC 60645-3 (only relevant to click stimuli – predicate to time compensated stimuli is not affected by this standard) IEC 60601-2-26 (see Chartr EP 200)
Workflow, Menu	**Same:** General workflow **Different:** Lower screen resolution, additional keys to enter data	**Same:** General workflow, online information and device control via header/footer	**Different:** PC-controlled with separate measurement platform.	**Different:** PC-controlled with separate measurement platform.

Parameter for Comparison	Cochlea-Scan	AccuScreen	Chartr EP 200	Eclipse
Available modules:	**Same:** DPOAE, TEOAE, DPTHRESHOLD, Standard Audiometry	**Same:** TEOAE, DPOAE, ABR **Different:** Sentiero offers diagnostic features instead of screening only	**Same:** ABR, ASSR	**Same:** ABR, ASSR
Interface to Computer, Software on Computer	**Same:** USB/RS232 connection	**Same:** USB connection, data transfer to PC Different: docking station.	**Different:** Runs on PC	**Different:** Runs on PC

Table 6-1: Comparison of device setup and technical features (Sentiero against different predicate devices)

Feature / Comparison	Titan with IMP440 (Predicate) 510(k) No. K083861	Sentiero	Comments
Indications for use	The Titan Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features tympanometry and acoustic reflexes.	Sentiero features tympanometry and acoustic reflexes.	Same
Target population	The devices are suitable for all populations including new-born infants	The devices are suitable for all populations including new-born infants	Same
Intended user	The devices are to be used by trained personnel only	The devices are to be used by trained personnel only	Same
Safety standard	IEC 60601-1	IEC 60601-1	Same
EMC standard	IEC 60601-1-2	IEC 60601-1-2	Same
Standards for impedance audiometry	IEC 60645-5/ANSI S3.39, Type 1	IEC 60645-5/ANSI S3.39, Type 1	Same
Test signal	IEC 60645-1/ANSI S3.6, IEC 60645-3	IEC 60645-1/ANSI S3.6, IEC 60645-3	Same
Probe tone frequency (tympanometry)	226 Hz. Optional 678 Hz, 800 Hz and 1000 Hz	226 Hz. 678 Hz, 800 Hz and 1000 Hz optionally available	Same

Probe tone level (tympanometry)	69 dB HL with AGC	69 dB HL with AGC	Same
Pressure safety limits	-750...+550 daPa	-700...+500 daPa	Equivalent Safety limits need to be within the range of -800...+600 daPa according to IEC 60645-5/ANSI S3.39, a smaller range means increased savety
Transducers	Ear probe for tympanometry, ear probe and headphone/insert ear phone for reflex measurement	Ear probe for tympanometry, ear probe and headphone/insert ear phone for reflex	Equivalent Different models of ear probe and headphones are used, all of them generating test signals complying to IEC 60645-5/ANSI S3.39 standards
Reflex stimuli	Pure tones at audiometric frequencies, narrow and wide band noise	Pure tones at audiometric frequencies, narrow and wide band noise	Same

TABLE 6-3: COMPARISON OF TEST MODULE TYMP

OVERALL CONCLUSION

The clinical tests showed that Sentiero can be used by professionals as efficiently as the respective predicate devices. The nonclinical tests shows that Sentiero is as similar safe, as effective and as performant as the predicate devices.

Target population	The devices are suitable for all populations including new-born infants	The devices are suitable for all populations including new-born infants	Same
Intended user	The devices are to be used by trained personnel only	The devices are to be used by trained personnel only	Same
Safety standard	IEC 60601-1	IEC 60601-1	Same
EMC standard	IEC 60601-1-2	IEC 60601-1-2	Same
Standards for impedance audiometry	IEC 60645-5/ANSI S3.39, Type 1	IEC 60645-5/ANSI S3.39, Type 1	Same
Test signal	IEC 60645-1/ANSI S3.6, IEC 60645-3	IEC 60645-1/ANSI S3.6, IEC 60645-3	Same
Probe tone frequency (tympanometry)	226 Hz. Optional 678 Hz, 800 Hz and 1000 Hz	226 Hz. 678 Hz, 800 Hz and 1000 Hz optionally available	Same
Probe tone level (tympanometry)	69 dB HL with AGC	69 dB HL with AGC	Same
Pressure safety limits	-750...+550 daPa	-700...+500 daPa	Equivalent Safety limits need to be within the range of -800...+600 daPa according to IEC 60645-5/ANSI S3.39, a smaller range means increased safety
Transducers	Ear probe for tympanometry, ear probe and headphone/insert ear	Ear probe for tympanometry, ear probe and headphone/insert ear	Equivalent Different models of ear probe and headphones are used, all of them

	phone for reflex measurement	phone for reflex	generating test signals complying to IEC 60645-5/ANSI S3.39 standards
Reflex stimuli	Pure tones at audiometric frequencies, narrow and wide band noise	Pure tones at audiometric frequencies, narrow and wide band noise	Same

TABLE 10-3: COMPARISON OF TEST MODULE TYMP

OVERALL CONCLUSION

Sentiero shows similar safety, effectiveness and performance data as the respective predicate devices.

CONCISE SUMMARY OF PERFORMANCE TESTING

Sentiero (all types and accessories) was tested by independent external laboratories with respect to the following standards:

- IEC **60601-1:1988**
- IEC **60601-1:2005**
- IEC **60601-1-2:2007**
- IEC **60601-2-40:1998**

Safety Safety Electromagnetic compatibility Safety of electromyographs and devices for evoked potentials

PATH medical GmbH is certified according to Medical Device Directive 93/42 ECC and holds certificates for compliance with respect to the following standards:

- ISO **9001:2008** Quality management system
- ISO **13485:2003** Quality management system (medical devices)

Basing on this, regular audits and compliance checks are performed by the following notified bodies:

- Notified body for certification in Europe: DEKRA Certification GmbH (Germany), (see certificate in the Appendix).
- Notified body for certification in Canada: DEKRA Certification B.V. (Netherlands), (see certificate in the Appendix).

Performance tests were also conducted on a test bench. For this reason a simulator device, which simulates TEOAE, DPOAE or ABR output was used for proof of validity of the derived signal. The same simulator device was distributed by Natus Europe GmbH as a testing device for the predicate devices AccuScreen and Cochlea-Scan.

The device under test (DUT) had to be connected to deliver the stimulus (via insert earphone or ear probe) into a cavity of the simulator. The output of the simulator was connected to the electrode cable of the DUT to record the test result. The stimulator was able to deliver noise or dedicated normative answers derived from literature. The same simulator was used for Sentiero as well as the predicate devices Cochlea-Scan and AccuScreen. The simulator was developed by the same engineers who developed the Cochlea-Scan as well as the AccuScreen. Passing the requirements given by the simulator was part of the acceptance criteria for the verification phase of the device development cycle. Consequently the performance of the test

modules TEOAE, DPOAE, DPTHRES, ABR were validated in comparison to the predicate devices during the in-house validation phase of Sentiero. The test protocol is attached in the Appendix.

Additionally Sentiero was tested against the following standards to show compliance and performance as follows:

- ISO **10993-1:2009** Biocompatibility
- IEC **60601-1-4:1996** Programmable electrical system
- IEC **60601-2-40:1998** Safety of electromyographs and devices for evoked potentials
- IEC **62304:2006** Software lifecycle

- IEC **60645-1:2001** Pure-tone audiometer
- IEC **60645-6:2009** Otoacoustic emissions
- IEC **60645-7:2009** Acoustically evoked potentials
- ISO **389-1:1998** Reference levels for pure tones and supra aural headphones
- ISO **389-2:1994** Reference levels for pure tones and insert earphones
- ISO **389-3:1994** Reference force levels for pure tones and bone conductors
- ISO **389-4:1994** Reference levels for narrow band masking noise
- ISO **389-5:2006** Reference levels for pure tones from 8 to 16 kHz
- ISO **389-8:2004** Reference levels for pure tones and circumaural headphones

Sentiero successfully passed the tests and checklists of the aforementioned standards. Thus it is shown that Sentiero is as safe, efficient and performing as the predicate devices which also fulfill the standards as mentioned in the comparison table above.

In preparation of the first application for receiving the CE mark for Sentiero, additional external, clinical test sites were asked to evaluate the performance of relevant test modules and the handling of the instrument. To state clearly: all implemented modules on Sentiero are derived from well-known algorithms, which are described in detail in published literature. The design process of Sentiero included in-house verification tests also with respect to the mentioned published literature and and establishment of normative data. In addition, external potential users were asked to validate the measurement results and the usage of the device and test modules (usability tests and performance tests). Comparison measurements had to be done with predicate devices and normal hearing patients as well as patients with hearing loss. Minimum number of participants per evaluation was 20. Multiple users should be involved to verify usability of the device in comparison to experience level of the user.

No tests were conducted with respect to animal testing.

The test sites, which participated in the evaluation of test modules on Sentiero are shown in *Table 10-4.* Please note that not all these testers and studies did receive financial support from PATH medical. Most of the evaluation data and feedback was contributed by initiative from the tester. The tester did not enter a financial arrangement with PATH medical – except the two sites mentioned in section 9 of this document, where PATH was the sponsor and initiator of the study.

Sentiero Module	Predicate device	Tester
PTA class 3 MAGIC (image-based pure tone audiometry) MATCH (image-based speech test) DPTHRES (DPOAE threshold estimation)	**Cochlea-Scan** (DPOAE threshold estimation) **Established speech tests** (e.g. Mainzer speech test for children)	Prof. Dr. med. Annerose Keilmann *Center of Communication Disorders, ENT Clinic, University Medical Center of the Johannes-Guttenberg-University Mainz, Mainz, Germany*
ABR	**Chartr EP 200**	Ph.D. Stavrous Hatzopoulos *Department of Audiology and Speech Therapy, University of Ferrara, Ferrara, Italy*
TEOAE DPQUICK (DPOAE at fixed levels) DPTHRES (DPOAE threshold estimation)	**AccuScreen** (TEOAE, DPOAE) **Cochlea-Scan** (DPOAE threshold estimation)	Prof. Dr. med. Hans Peter Niedermeyer *ENT Clinic, Klinikum rechts der Isar, Technische Universität München, Munich, Germany*
ASSR	**ECLIPSE**	Dr. Thomas Rosner *ENT Clinic, Klinikum rechts der Isar, Technische*

Sentiero Module	Predicate device	Tester
		Universität München, Munich, Germany
ABR	ABR device, unknown type.	PD Dr. med. Nicolas Schmuziger ENT Clinic, Kantonsspital Liestal, Liestal, Switzerland
PTA MAGIC (image-based pure tone audiometry) TEOAE DPQUICK (DPOAE at fixed levels) DPTHRES (DPOAE threshold estimation) ABR	EchoScreen/AccuScreen and CochleaScan	Prof. Dr. Katrin Neumann Department of Phoniatry and Pedaudiology, ENT Clinic, St.-Elisabeth-Hospital, Bochum, Germany

Table 10-4: List of external tests including tested module and the corresponding tester

Out of these studies reports were generated or published, which indicated that Sentiero is an equivalence to the given predicate devices with respect to clinical application/usage.

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

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