June 22, 2022

Path Medical GmbH
Johann Oswald
Managing Director
Landsberger Strasse 65
Germering, Bavaria 82110
Germany

Re: K213345
Trade/Device Name: Sentiero, AuDX, AuDX PRO, Sentiero Desktop, AuDX PRO Flex, Sentiero Advanced, NavPRO ONE
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ, ETY
Dated: May 17, 2022
Received: May 20, 2022

Dear Johann 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213345

Device Name
Sentiero

Indications for Use *(Describe)*
Devices of the Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics and vestibular diagnostics (Sentiero Advanced only).

Available psycho-acoustical methods on Sentiero devices are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do play/interactive audiometry. Physiological modules which require active patient participation (e.g. VEMP) are indicated for use with cooperative patients who are mentally and physically able to perform the required task. All other physiological 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.

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.

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510(k) Summary

I. SUBMISSION INFORMATION

Date of preparation:	June 15th, 2022
510(k) Submitter:	PATH MEDICAL GmbH Landsberger Str. 65 82110 Germering Germany Phone: ++49-89-80076502 Fax: ++49-89-80076503
Contact Person:	Dr. Johann Oswald, Director Landsberger Str. 65 82110 Germering Germany Phone: ++49-89-80076502 Fax: ++49-89-80076503 Email: oswald@pathme.de

II. DEVICE INFORMATION

Device Name:	SENTIERO
Device Trade Names:	Sentiero, Sentiero Screening, Sentiero Diagnostic, Sentiero Advanced, Sentiero Desktop, AuDX, AuDX PRO, AuDX PRO FLEX, NavPRO ONE
Device Identification Codes:	SOH1000098, SOH100360, SOD100497
Common Name:	Evoked Response Auditory Stimulator
Classification Name:	Evoked Response Auditory Stimulator, Audiometer, Auditory Impedance Tester FDA 21CFR882.1900 & 21CFR874.1050 & 21CFR874.1090

III. PREDICATE DEVICE

SENTIERO	510(k) Number: K133012

This device has not been subject to a recall.

IV. REFERENCE DEVICE

Eclipse with VEMP	510(k) Number: K162037

V. 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. 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.

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.

The measurement application is controlled from a self-contained firmware. 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 are displayed for the user's evaluation.

The patient/test data can be transferred from the device to a PC via a USB connection and the accompanied data management and archiving software MIRA. Patient/test data on the device and on the PC software can be password- protected so that unauthorized access is prohibited.

Compared to the original 510(k) submission of the Sentiero in its predicate state, the Sentiero now offers a VEMP test module. Vestibular evoked myogenic potential (VEMP) is a short latency muscle reflex driven by otolithic organs that play a major role for detecting the orientation, static balance and linear acceleration of the head. Vestibular dysfunctions arise from various different regions along the vestibular pathway. Vestibular neuritis, vestibular schwannoma, multiple sclerosis, otosclerosis or Meniere's disease will be indicated by the decrease or absence of VEMP responses.

INTENDED USE

Devices of the Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics and vestibular diagnostics (Sentiero Advanced only). Devices of the Sentiero device family provide standard psychoacoustical test procedures and additionally physiological test procedures including otoacoustic emissions (OAE) (e.g. transitory evoked otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE)), evoked potentials (e.g. auditory brainstem responses (ABR), auditory steady state responses (ASSR); vestibular evoked myogenic potentials (VEMP)) (Sentiero Advanced only), and auditory impedance and acoustic reflex measurements (Sentiero Desktop, Sentiero and Sentiero Advanced with tympanometry add-on).

Available psycho-acoustical methods on Sentiero devices are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do

play/interactive audiometry. Physiological modules which require active patient participation (e.g. VEMP) are indicated for use with cooperative patients who are able to mentally and physically perform the required task. All other physiological 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.

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 or vestibular disorders. Estimation of cochlear hearing thresholds (DPOAE Threshold) is possible at various frequencies without the need of cooperative interaction with the patient. Acoustic reflex and tympanometry are featured to evaluate the functional condition of the middle and outer ear. VEMP is featured to assist in the evaluation of the functional condition of the vestibular system. For each method, several protocols can be configured. The results can be used to make further recommendations regarding appropriate intervention strategies.

Devices of the Sentiero device family are intended for the following purposes:

- Diagnostics, monitoring and follow-up after newborn hearing screening
- Pre-school, school, and adult hearing screening
- ENT diagnostics based on measurement of
  a) Otoacoustic emissions
  b) Tympanometry and acoustic reflex (Sentiero Desktop, Sentiero and Sentiero Advanced with tympanometry add-on)
  c) Evoked potentials (Sentiero Advanced only)

Sentiero is intended for use by audiologists, ear-nose-throat (ENT) doctors, and other hearing/ENT health care professionals and personnel trained on the available test modules in a medical environment. Please consider local regulations regarding the qualification requirements for performing measurements with a specific test module.

Sentiero is not intended for operational use by the general public. All test procedures must be supervised or conducted by qualified personnel. In the United States of America, Federal law restricts this device to sale by or on the order of a licensed physician.

Sentiero is intended for indoor-use only and must be operated at defined environmental conditions. Sentiero is not intended for use in oxygen-rich environments.

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. cVEMP on Sentiero Advanced must not be used in cases of neck, muscular and cervical injury problems and in cervical spine problems if the sternocleidomastoid muscle contraction cannot be maintained without further discomfort or pain.

VI. COMPARISONS

The Sentiero with VEMP will be compared to the predicate Sentiero ABR (without VEMP) due to the use of the same hardware, basic operating principle, and classification code (GWJ). For the parameters of the VEMP test module, the subject device will be compared to the reference device Eclipse with VEMP.

COMPARISON TO PREDICATE DEVICE

For an easier comparison, the new VEMP module will be compared to predicate Sentiero's existing ABR module instead of all existing Sentiero test modules and their different operating principles. The new VEMP module and the existing ABR module use the same stimulus types, accessories and basic operating principle.

	Sentiero ABR (without VEMP)	Sentiero VEMP	Equivalency
Intended Purpose			
Intended use	Detection of otologic disorders through evoked potentials (EP) by Audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals and audiologically trained technicians.	Detection of vestibular disorders through evoked potentials (EP) by Audiologists, ear-nose-throat (ENT) doctors, and other hearing/ENT health care professionals and personnel trained on the available test modules.	Similar, both detect inner ear disorders through Evoked Potentials. Intended User is the same.
Indications for Use	Devices of the Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics. Available psycho-acoustical methods on Sentiero are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do play/interactive audiometry. All other physiological 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.	Devices of the Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics and vestibular diagnostics (Sentiero Advanced only). Available psycho-acoustical methods on Sentiero devices are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do play/interactive audiometry. Physiological modules which require active patient participation (e.g. VEMP) are indicated for use with cooperative patients who are mentally and physically able to perform the required task. All other physiological modules are suitable to be	Similar. New indications for use also lists VEMP; both diagnostics performed by ENT specialists to detect inner ear disorders through EPs.

	Sentiero ABR (without VEMP)	Sentiero VEMP	Equivalency
		used for all ages elder than infants from 34 weeks (gestational age) that are ready for discharge from the hospital.	
Physiological features			
Biosignal	Evoked potential	Evoked potential	Same
Electrode position	Head and neck	Head, neck and sternoclavicular junction (cVEMP) or extraocular muscle (oVEMP)	Not exactly the same positions but similar
Stimulation target	Cochlea	Circular ducts	Similar, both are structures of the inner ear
Biosignal Generator	Auditory pathway	Myogenic system	Similar
Patient cooperation	Calm and relaxed posture to minimize myogenic noise.	Calm and relaxed posture to minimize myogenic noise. Patient should turn head to contract sternocleidomastoid muscle (cVEMP) or keep an upward gaze of 35° to contract extraocular muscle (oVEMP).	Same. Movement should be kept at a minimum to reduce noise. The turning of the head or the upward gaze is just one additional part of the initial setup.
Hardware			
Hardware	Sentiero Advanced	Sentiero Advanced	Same
Transducer	Headphone / Insert phone, bone conductor, ear coupler cable, or ear probe	Headphone / Insert phone, bone conductor	Same (subset)
Potential recording	EEG sensors and PATH MEDICAL electrode cable	EEG sensors and PATH MEDICAL electrode cable	Same
EEG recording channels, number of electrode contacts	1, 3	1, 3	Same
Communication interfaces	USB connection to a PC;	USB connection to a PC;	Same

	Sentiero ABR (without VEMP)	Sentiero VEMP	Equivalency
	Proprietary connector (label printer only)	Proprietary connector (label printer only)	
Applied standards	All relevant biocompatibility, electrical safety, usability, audiological and medical device manufacturing standards	All relevant biocompatibility, electrical safety, usability, audiological and medical device manufacturing standards	Same
Implementation Details			
Stimuli	Click, Chirp, Tone Burst	Click, Chirp, Tone Burst	Same
Stimulus repetition rate	10-100 Hz	2-10 Hz	Similar (adjacent range)
Stimulus levels	0-100 dB nHL	20-110 dB nHL	Similar
Result representation	Time domain waveform plot with wave I, III, V markers, plot range: 0-25 ms	Time domain waveform plot with P1, N1 markers, plot range: 40-100 ms	Similar (markers have different names, different plot range)
Result interpretation	by ENT specialist	by ENT specialist	Same

COMPARISON TO REFERENCE DEVICE

	Reference Device Eclipse with VEMP	Subject Device Sentiero VEMP	Equivalency
Indications for Use	The Eclipse with VEMP (Vestibular Evoked Myogenic Potential) is intended for vestibular evoked myogenic potential testing to assist in the assessment of vestibular function. The target population for Eclipse with VEMP includes patients aged from 8 years and up. The device is to be used only by qualified medical personnel	Devices of the Sentiero device families offer different test methods which can be configured to fit the professional's needs for hearing screening or diagnostics and vestibular diagnostics (Sentiero Advanced only). Available psycho-acoustical methods on Sentiero devices	Similar, both devices are (amongst others) indicated for use in vestibular diagnostics. The difference in patient age does not raise any concerns regarding safety or effectiveness

	with prior knowledge of the medical and scientific facts underlying the procedure.	are especially indicated for use with cooperative patients starting at the age of two years or adequate development age, which enables them to do play/interactive audiometry. Physiological modules which require active patient participation (e.g. VEMP) are indicated for use with cooperative patients who are able to perform the required task. All other physiological 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.	as the limiting factor has been shown to be patient cooperation and not age. Patient cooperation is ensured through EMG Monitor and trained, professional users.
EEG recording channels, number of electrode contacts	2, 4	1, 3	Similar, Sentiero VEMP requires sequential testing if both sides are tested.
Available transducers	Headphones, Insert Earphones, bone conductor, OAE probe, speakers	Headphone / Insert Earphone, bone conductor	Similar, subset
EMG monitor	Range indicating the current and optimal EMG readings.	Range indicating the current and optimal EMG readings.	Same
Stimulus implementation			
Stimulus types	Click, Chirp, Tone Burst	Click, Chirp, Tone Burst	Same
Stimulus repetition rate	0.1-100 Hz	2-10 Hz	Different, both cover the range usually used for VEMP.
Polarity	Rarefaction, Condensation, Alternating	Rarefaction, Condensation, Alternating, Randomized	Similar, Randomized is just one of the other three
Frequency range	125 Hz- 16000 Hz	500 Hz – 4000 Hz	Smaller range, covers the most relevant

			frequency range for VEMPs
Filter	Rectangular, Hann, Blackman, Gaussian, Trapezoidal, Extended Cosine, Barlett, Cosine Cubed, Exact Blackman	Linear, Blackman	Similar, subset
Presentation	Right, left, both sides	Right, left, both sides	Same
Results			
EMG scaling	Yes	Yes	Same
Result presentation	Time domain waveform plot with P1, N1 markers	Time domain waveform plot with P1, N1 markers	Same
Automatic asymmetry calculation	Yes	Yes	Same
Result interpretation	Only presentation of recorded potential and asymmetry. No diagnosis by the device. ENT specialist interprets the results.	Only presentation of recorded potential and asymmetry. No diagnosis by the device. ENT specialist interprets the results.	Same

Safety and Effectiveness comparison to the predicate and reference device:

The Sentiero with VEMP module is identical in hardware and technological aspects to the predicate device.

With respect to the intended use, the new VEMP module extends the intended use with evoking and detecting vestibular myogenic evoked potentials for vestibular diagnostics.

The implementation of the VEMP test module is similar to the already cleared reference device Eclipse with VEMP.

Biocompatibility testing

The biocompatibility evaluation was conducted according to ISO 10993-1:2009. Following tests were considered applicable:

- Cytotoxicity
- Sensitization
- Irritation

The device and its accessories are classified as short-term contact and contact with intact skin. No issues were found during biocompatibility testing.

Electrical safety and electromagnetic compatibility (EMC)

The Sentiero was tested according to and complies to following electrical safety and electromagnetic compatibility standards: IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, IEC 60601-2-40:1998 and 2016.

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, since a failure or latent flaw in the software are unlikely to cause any injury to the patient or operator.

Mechanical and Acoustic Testing:

- Maximum possible sound level compliant to IEC 60601-1 and 60601-2-40.
- Push, Drop, and Mould Stress Relief test as part of IEC 60601-1 test for portable devices.

Clinical Evaluation

Obtaining VEMP is a well-documented procedure to detect possible dysfunctions of the vestibular system. The Sentiero with VEMP module offers the same transducers, stimulus types and frequency ranges typically found in academic papers on VEMP measurements. Additionally, it supports threshold estimation, cVEMP and oVEMP testing and interpeak amplitude comparison to provide assistance to ENT doctors for a diagnosis of the vestibular system. A detailed clinical evaluation was conducted to confirm that the implementation of VEMP in the Sentiero represents the current State of the Art.

Furthermore, the EP recording function of the predicate Sentiero, which was already in use for several years in its ABR modules, was again tested for overall performance as well as repeatability and reliability for the new use-case.

The parameters of the conducted tests were as follows:

Test subjects	16 normal hearing adults
Performed tests	cVEMP and oVEMP
Number of traces per day and VEMP modus	2
Stimulus	Tone Burst Blackman 2-1-2, 65 dB HL
Transducer	Bone Conductor B81
Rate	5.1 Hz
Polarity	Alternating
Frequency	500Hz
Sweeps per trace	150

Results:

Repeatability [Coefficient of variation]:

	P1 latency [%]	N1 latency [%]	Interpeak latency [%]	Interpeak Amplitude [%]
Day 1 [oVEMP]	1.95	1.23	7.54	8.02
Day 2 [oVEMP]	1.02	1.69	6.72	12.14
Day 1 [cVEMP]	1.25	1.85	5.40	11.48
Day 2 [cVEMP]	2.51	1.21	5.40	7.08

Reliability [Coefficient of variation]:

	P1 latency [%]	N1 latency [%]	Interpeak latency [%]	Interpeak Amplitude [%]
Day 1 & Day 2 [oVEMP]	2.98	2.38	10.86	23.64
Day 1 & Day 2 [cVEMP]	3.32	4.05	11.15	18.80

The subject device produced results similar to the data typically found in academic literature. Repeatability and reliability tests showed a low variation in latency of the P and N marker and interpeak latency difference, and a medium variation in interpeak amplitude results. Overall, the EP system as implemented in the subject Sentiero with VEMP can be considered suitable for the recording of VEMPs to assist ENT Doctors in a diagnosis of deficiencies in the vestibular system.

VII. SUMMARY

VEMP, like ABR, is an acoustically evoked potential which can be obtained using commercially available EP systems. The Sentiero VEMP module has the ability to perform EMG monitoring during VEMP data collection. The VEMP module of the Sentiero does not provide a diagnosis. The diagnosis is made by a qualified medical professional, while the Sentiero device only collects these potentials and displays them analogue to the approach used for other AEP measurements like ABR or ASSR. Testing the vestibular evoked myogenic potential (VEMP) is well- documented in the literature.

VIII. Substantial Equivalency

The Sentiero with VEMP and the predicate Sentiero use the identical hardware and accessories. Additionally, the operating principle behind the measurement of VEMPs is identical to the ABR operating principle as both record an acoustically evoked potential for a diagnosis. The relevant differences are the increased stimulus level needed for VEMP and the change of the biosignal generator and subsequent change of Indications for Use.

Bench tests verified, that the maximum available stimulus level remains below possibly hazardous overexposure. Measuring VEMP is a well-documented procedure and was implemented similarly to the application in academic papers to account for the change in biosignal generators. Similar to the ABR module, the VEMP module only shows the recorded potentials and does not provide a diagnosis. Recording acoustically evoked potentials has been performed for years on the predicate device with the ABR module and has been tested for the VEMP module in a test-retest test, where sufficient repeatability and reliability was proven.

The implementation of the VEMP module has been found to be very similar in terms of available transducers, stimulus parameters and result presentation to the reference Eclipse with VEMP.

It can be concluded, that the Sentiero with VEMP does not affect the safety and effectiveness and introduces no significant technological changes, therefore it can be considered substantially equivalent to the Sentiero without VEMP.

IX. OVERALL CONCLUSION

The Sentiero with the addition of the VEMP module shows identical characteristics in biocompatibility, software design, electrical safety and compatibility, and user testing compared to the predicate Sentiero without VEMP module. The extension of the indicated use does not raise different questions of safety and effectiveness and only differs through addition of the VEMP module and the reference to vestibular diagnostics. Additionally, there were no changes of the hardware and technological characteristics. Therefore, the Sentiero with VEMP can be considered substantially equivalent to the predicate Sentiero without VEMP module.