August 3, 2022

PATH MEDICAL GmbH
Johann Oswald
Managing Director
Landsberger Strasse 65
Germering, Bavaria 82110
Germany

Re: K220139
Trade/Device Name: QScreen
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ, EWO
Dated: January 12, 2022
Received: July 7, 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)*
K220139

Device Name
QScreen

Indications for Use *(Describe)*
The QSCREEN device is a hand-held, portable hearing screener intended for recording and automated evaluation of Otoacoustic Emissions (OAE) and Auditory Brainstem Responses (ABR). Distortion Product Otoacoustic Emission (DPOAE) and Transient Evoked Otoacoustic Emission (TEOAE) tests are applicable to obtain objective evidence of peripheral auditory function. ABR tests are applicable to obtain objective evidence of peripheral and retro-cochlear auditory function including the auditory nerve and the brainstem. QSCREEN is intended to be used in subjects of all ages. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable.

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

SUBMISSION INFORMATION

Date of preparation:	August 3, 2022
510(k) Submitter:	PATH MEDICAL GmbH Landsberger Str. 65 82110 Germering Germany Phone: ++49-89-80076502 Fax: ++49-89-80076503
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DEVICE INFORMATION

Device Name:	QScreen
Device Trade Names:	QScreen
Device Identification Codes:	PM1610
Common Name:	Evoked Response Auditory Stimulator
Classification Name:	Evoked Response Auditory Stimulator FDA 21CFR882.1900 & 21CFR874.1050

PREDICATE DEVICE

Sentiero	510(k) Number: K133012

DEVICE DESCRIPTION

The QScreen is a hand-held and portable audiometric examination device offering test methods for the measurement of Otoacoustic Emissions (OAE) including transitory evoked otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE) and Auditory Evoked Responses like Auditory Brainstem Responses (ABR) in patients of all ages. It has a touch screen display and can be used with different accessories, such as its Docking Station, Ear Coupler Cable, Ear probe, Insert earphone, and Electrode cable.

QScreen is a battery powered device which is charged by the Docking Station wirelessly and communicates with the Docking Station via Bluetooth. The Docking Station can be connected to a personal computer (PC) via USB cable on which patient and test data can be reviewed and managed with the optional software. Additionally, device and user profile configurations can be conducted with the software. Printing the data is also possible and carried out by a label printer that can be connected to the Docking Station. The QScreen device also contains a camera on the back side to read linear bar codes and QR codes. All materials that come into contact with human skin are selected to be biocompatible.

The operating system on the QScreen is a self-contained firmware. The user is guided by the menu on the touch screen through the measurement. The results are evaluated on the base of signal statistics. The device offers an automatically created result, which can have the values "PASS" (Clear Response), "REFER" (No Clear Response) or "INCOMPLETE" (Test aborted).

The following accessories are available to conduct a measurement:

- EP-LT (Longitudinal ear probe)
- EP-DP
- PIEP (PATH Insert Earphone)
- PECC (PATH Ear Coupler Cable) with Ear Couplers
- Electrode cable (shielded, passive cable to connect the instrument to electrodes)
- Headphone

These accessories can be connected to QScreen using special colored and mechanical coded plugs with memory chips, which hold the information about the connected transducer / cable, such as its correct and supported connection to the device and further stored information like calibration data and the status of the cable. By that, the firmware can make use of this information and adapt the measurement procedure according to calibration values or provide information to the user via its display.

COMPARISON TO THE PREDICATE DEVICE:

	QScreen (subject)	**Sentiero (predicate)**	**Equivalency**
Intended purpose			
Intended Use	The QScreen offers methods for Screening for OAEs (TEOAE and DPOAE) and ABR. QScreen is to be used by audiologists, ear-nose-throat (ENT) doctors, and other hearing health care professionals, nurses and audiologically trained personnel. It is not intended to be operated by lay users.	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. In addition, the Sentiero offers methods for Screening (TEOAE,	Different: Sentiero offers more test modules. The modules available on the QScreen are a subset of the modules available on the Sentiero.

	QScreen is intended for indoor-use only and must be operated at defined environmental conditions. QScreen is not intended for use in oxygen-rich environments.	DPOAE) as well as diagnostics (Audiometry, OAE, AEP measurements, Tympanometry). Sentiero is intended for use by trained personnel such as audiologists, pediatricians, ENT doctors and other health care professionals.	Same: Both devices are limited to professional users.
Indications for Use	The QScreen device is a hand-held, portable hearing screener intended for recording and automated evaluation of Otoacoustic Emissions (OAE) and Auditory Brainstem Responses (ABR). Distortion Product Otoacoustic Emission (DPOAE) and Transient Evoked Otoacoustic Emission (TEOAE) tests are applicable to obtain objective evidence of peripheral auditory function. ABR tests are applicable to obtain objective evidence of peripheral and retro-cochlear auditory function including the auditory nerve and the brainstem. QScreen is intended to be used in subjects of all ages. It is especially indicated for use in testing individuals for whom behavioral audiometric results are deemed unreliable.	Sentiero is a portable instrument to diagnose all ages for hearing loss. 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. 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 a. Otoacoustic emissions b. Tympanometry and acoustic reflex c. Auditory Brainstem Responses d. Auditory Steady State Responses	Different: QScreen IFU is a subset of Sentiero. The diagnostic modules in the Sentiero are not available in the QScreen.
Physiological features			
Biosignal	Evoked potential, Evoked emissions	Evoked potential, Evoked emissions	Same

Electrode position	Forehead, nape of neck and cheek	Forehead, nape of neck and cheek	Same
Stimulation target	Cochlea	Cochlea	Same
EEG recording channels, number of electrode contacts	1,3	1,3	Same
Accessories			
Transducer	Ear probes, Insert earphones, Ear coupler cable, Headphones manufactured by PATH MEDICAL	Ear probes, Insert earphones, Ear coupler cable, Headphones manufactured by PATH MEDICAL	Same
Electrode Cable	PATH MEDICAL Electrode Cable (shielded, 3 clamps)	PATH MEDICAL Electrode Cable, (shielded, 3 clamps)	Same
Electrodes	Snap Hydrogel-electrodes	Snap Hydrogel-electrodes	Same
Ear Coupler	PATH MEDICAL Ear Coupler	PATH MEDICAL Ear Coupler	Same
Probe Tips + Ear Tips	PATH MEDICAL Probe tips + Ear Tips	PATH MEDICAL Probe tips + Ear Tips	Same
Implementation details			
Measuring method ABR	• Chirp stimulus • 85 Hz ± 10% stimulus repetition rate (randomized) • 30, 35, 40, 45 dB nHL stimulus level • noise-weighted averaging and template matching with statistical evaluation • Result interpretation: By the device	• Chirp stimulus • 85 Hz ± 10% stimulus repetition rate (randomized) • 30, 35, 40, 45 dB nHL stimulus level • noise-weighted averaging and template matching with statistical evaluation • Result interpretation: By the device	Different: More stimuli and protocols available on the Sentiero for diagnostic ABR. The available protocols and stimuli on the QScreen are a subset of the Sentiero.
Measuring method OAE	• TEOAE: Click stimulus • DPOAE: Sinusoidal tones • TEOAE: 59-76 Hz stimulus repetition rate (randomized) • TEOAE: 85 dB peSPL stimulus level • noise-weighted averaging with statistical evaluation • Result interpretation: By the device	• TEOAE: Click stimulus • DPOAE: Sinusoidal tones • TEOAE: 59-76 Hz stimulus repetition rate (randomized) • TEOAE: 85 dB peSPL stimulus level • noise-weighted averaging with statistical evaluation • Result interpretation: By the device	Different: More stimuli and protocols available on the Sentiero for diagnostic OAE. The available protocols and stimuli on the QScreen are a subset of the Sentiero.
Screening options	Each ear individually or simultaneously	Each ear individually or simultaneously	Same
Result interpretation	By the device	By the device	Same

Result repre-sentation	PASS/REFER/INCOMPLETE	PASS/REFER/INCOMPLETE	Same
Technological details			
Hardware setup	Standalone, handheld / portable device, battery powered. Operated via Touch Screen. Can be charged using a Docking Station.	Standalone, handheld / portable device, battery powered. Operated via Touch Screen.	Different: Identical except the Sentiero does not use a docking station. Electrical safety tests included the docking station.
Workflow	Operation via Touch Screen. Screen layout: header, main panel, footer for navigation. GUI: The home screen: 3x3 tile lay-out having access to the main features of the device.	Operation via Touch Screen. Screen layout: header, main panel, footer for navigation. GUI: List layout	Different: QScreen uses grid layout due to the reduced number of available options compared to the Sentiero.
Interface to Computer, Software on Computer	Data Transfer via Bluetooth to Docking Station and USB data transfer from Docking station to PC.	Data Transfer via USB cable to PC.	Different: The QScreen additionally uses an FCC certified Bluetooth module.
Device Firm-ware:	The firmware architecture is based on a proprietary operating system: runtime-model based on a graphical user interface library, which processes user input and updates the touch screen. Firmware is based on PATH's Sentiero device family. Basic functionalities like measurement algorithms, patient and user management, communication protocols, localization, etc. share common code. QScreen specific modules (i.e. barcode reader) are added to the basic firmware.	The firmware architecture is based on a proprietary operat-ing system: runtime-model based on a graphical user in-terface library, which processes user input and updates the touch screen. Firmware is based on PATH's Sentiero device family. Basic functionalities like measure-ment algorithms, patient and user management, communi-cation protocols, localization, etc. share common code.	Different: QScreen mod-ules are a sub-set of the Sen-tiero modules. Barcode scan-ner has no influ-ence on safety or effectiveness of the device.
PC Software	PC Software for data analysis and archiving.	PC Software for data analysis and archiving.	Same

Battery, Charger	Battery- driven using Li-Ion technology (10.4Wh), medical grade charger, no user-exchangeable battery.	Battery-driven NiMH (7.2Wh) in Sentiero Handheld/ Li-Ion (9.6Wh) in Sentiero Desktop, medical grade charger, no user-exchangeable battery.	Same type as Sentiero Desktop. Slightly higher capacity will have no effect on safety or effectiveness.

Table 5. 1 Comparison to predicate device

Non-Clinical Performance Data:

Biocompatibility testing:
The biocompatibility evaluation was conducted according to ISO 10993-1:2018. Following tests were applied:

- Cytotoxicity according to ISO 10993-5:2009
- Sensitization according to ISO 10993-10:2010
- Irritation according to ISO 10993-10:2010

Electrical safety and electromagnetic compatibility (EMC):
The QScreen 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 (including Bluetooth and wireless charging features), IEC 60601-2-40: 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 life cycle standard IEC 62304:2015 was applied during the development process.

Usability Testing:
The QScreen has been developed and tested according to the Usability standard EN 62366:2015 including extensive risk assessment and mitigation, user interface evaluations, and identification of the primary operating functions.

Mechanical and Acoustic Testing:

- Maximum possible sound level will remain below a possibly threatening level even under electrical failure
- Push, Drop, and Mould Stress Relief test
- Frequency content, timing, sound level, and repetition rate of the stimuli equivalent to the predicate Sentiero's stimuli

Literature Review:
A clinical evaluation of the QScreen showed that the implementation of ABR and OAE screening on the subject device matches the current state of the art.

The template and basic ABR algorithm implemented on Sentiero and QScreen devices are discussed in the following publications:

Peters, J. G. "An automated infant screener using advanced evoked response technology." *The Hearing Journal* 39 (1986): 25-30.

Cabana-Pérez, I.M.; et al. "Automatic ABR detection at near-threshold intensities combining template-based approach and energy analysis." *VII Latin American Congress on Biomedical Engineering CLAIB* 2016

Herrmann, Barbara S., Aaron R. Thornton, and Janet M. Joseph. "Automated infant hearing screening using the ABR: development and validation." *American Journal of Audiology* 4.2 (1995): 6-14.

Clinical Performance Data:

No clinical performance data was collected for the subject device QScreen. Substantial equivalence was shown through bench testing and compliance to international standards (IEC 60645-6:2009 (OAE) and IEC 60645-7:2009 (ABR)).

SUBSTANTIAL EQUIVALENCE

The QScreen device utilizes the same methods, stimulus parameters and accessories to evoke, record, process and detect ABR and OAE responses as implemented in the predicate Sentiero.

Bench testing was performed for relevant audiological characteristics of the stimulus delivered to the patient as well as interpretation of the recorded potential. These tests included frequency, timing and sound level of the stimulus as well as noise resistance and the lowest response signal detectable by the device. The results show the substantial equivalence of the subject device to the predicate device in terms of non-clinical performance.

Additionally, biocompatibility, electrical safety, and EMC testing was conducted by independent laboratories to demonstrate that the subject device is as safe and as effective as the predicate device.

The QScreen uses the same material and manufacturers for the housing, sockets, plugs, charger, display, PCB and the accessories as the predicate Sentiero device.

OVERALL CONCLUSION

The comparison between QScreen and the predicate Sentiero reveal comparable technical characteristics such as test parameters, recording techniques, and accessories. As the QScreen has a subset of the functionality of the Sentiero device, differences in the scope of testing and indications for use do not raise different question of safety or effectiveness.

The QScreen can be considered substantially equivalent to the predicate Sentiero in terms of technological aspects and indications for use.