March 15, 2024

Otodynamics Ltd
℅ Chandler Thames
Director of Quality
Rook Quality Systems
1155 Mount Vernon Hwy #800
Dunwoody, Georgia 30338

Re: K240430
Trade/Device Name: Otoport Pro
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: February 12, 2024
Received: February 14, 2024

Dear Chandler Thames:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shuchen Peng -S

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)*
K240430

Device Name
Otoport Pro

Indications for Use *(Describe)*

The Otoport Pro device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. ABR, TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization.

Where the individual to be screened is healthy with no medical conditions related to the ear, as in the case of well-baby hearing screening, the user can be a trained screener. In all other cases the user should be an audiologist or medical professional.

The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose, the device is intended to be used by audiologists or other professionals skilled in audiology. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.

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)

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SUBMITTER

Otodynamics Ltd
30-38 Beaconsfield Rd
Hatfield, Hertfordshire
ALl0 8BB, United Kingdom

Phone: +44 1707 267540
Email: daniel.budd@otodynamics.com

Contact Person: Daniel Budd, QA Manager
Date Prepared: 15.03.2024

DEVICE

Trade Name:	Otoport Pro
Common Name:	Otoport Pro
Classification Name:	Audiometer/ Evoked response auditory stimulator (874.1050 & 882.1900)
Regulatory Class:	Class II
Product Codes:	EWO &GWJ

PREDICATE DEVICE

The legally marketed device to which equivalence is being claimed [807.92(a)(3)] is the Otoport/Otocheck OAE+ABR™, K143395.

This predicate has not been the subject of any design-related recalls.

DEVICE DESCRIPTION

The Otodynamics Ltd ("Otodynamics") Otoport Pro device is a compact handheld device capable of high quality OAE measurements for clinical purposes and also automated ABR and OAE testing for fast infant screening.

Responses to sound are recorded via an applied earphone and or adhesive surface electrode pad. Specifically, the device can record Otoacoustic Emissions (type DPOAEs or TEOAEs) and auditory brainstem responses (ABRs) to sound. These responses are especially useful in the hearing screening of infants for deafness. The more detailed analysis of DPOAE and TEOAE responses is additionally useful as a component of the audiological diagnostic test battery.

The Otoport Pro is simple to use with customizable automation to make testing easy and the results clear. It has user access controls, graphical display panel, and extensive test database features. The Otoport Pro when configured for clinical use has advanced test features including extensive raw data capture for offline review and analysis if required.

Otoport Pro device is a hardware/ software revision of the currently marketed **Otoport OAE+ABR,** having the same performance and intended uses as the Otoport OAE+ABR device.
The previous version of the Otoport product (Otoport OAE+ABR) required an adaptor 'shell' to be fitted over the base unit if AABR functionality was required (Figure 1 below)

In the Otoport Pro design (Figure 2 below) all test modalities are included inside the base unit.

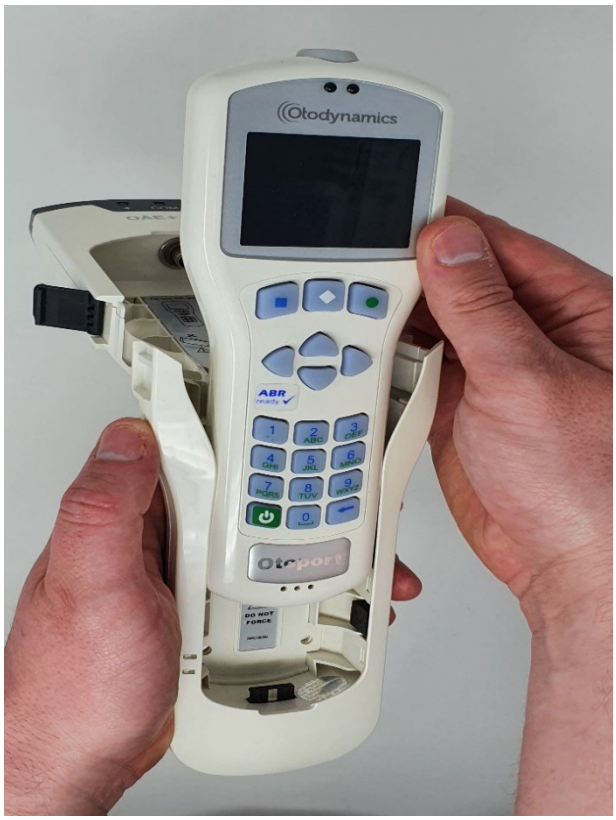

Figure 1

Figure 2

INDICATIONS FOR USE

The Otoport Pro device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. ABR, TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization. Where the individual to be screened is healthy with no medical conditions related to the ear, as in the case of well-baby hearing screening, the user can be trained. In all other cases the user should be an audiologist or medical professional. The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose, the device is intended to be used by audiologists or other professionals skilled in audiology. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The same Otoacoustic Emissions (OAEs) & Auditory Brainstem Response (ABR) techniques and principles of response analysis are utilized in both the subject and predicate devices.

TABLE 1. COMPARISON BETWEEN THE SUBJECT DEVICE AND THE PREDICATE OTOPORT/OTOCHECK 0AE+ABR (K143395)

	Subject Device Otoport Pro (K240430)	**Predicate Device Otoport/ Otocheck OAE+ABR (K143395)**	**Overview of similarities and differences**
Common Name	Audiometer Evoked response auditory stimulator	Audiometer Evoked response auditory stimulator	Same
Class	II	II	Same
Product Code	EWO&GWJ	EWO&GWJ	Same
Classification Regulation	874.1050 882.1900	874.1050 882.1900	Same
Intended Use	For the detection of peripheral hearing loss and for use in the characterization of and diagnosis of auditory and hearing-related disorders.	For the detection of peripheral hearing loss and for use in the characterization of and diagnosis of auditory and hearing-related disorders.	Same
Indications for Use	The Otoport Pro device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. ABR, TEOAE and DPOAE screening test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization. Where the individual to be screened is healthy with no medical conditions related to the ear, as in the case of well-baby hearing screening, the user can be a trained screener. In all other cases the user should be an audiologist or medical professional. The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose, the device is intended to be used by audiologists or other professionals skilled in audiology. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.	The Otoport/Otocheck OAE+ABR device is indicated for use when there is a requirement to screen for hearing disorders by objective and non-invasive means. Test results are automatically interpreted and a clear 'Pass' or 'Refer' result is presented to the user. Use of the device is indicated when the patient is unable to give reliable voluntary responses to sound, especially with infants. Use of the device facilitates the early detection of hearing loss and its characterization. Where the individual to be screened is healthy with no medical conditions related to the ear, as in the case of well-baby hearing screening, the user can be a trained screener. In all other cases the user should be an audiologist or medical professional. The TEOAE and DPOAE analytical functions of the device are indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function. For this purpose, the device is intended to be used by audiologists or other professionals skilled in audiology. These TEOAE and DPOAE tests are applicable to populations of any age to obtain objective evidence of peripheral auditory function.	Same

Overall Device Design	Handheld device (L195mm x W70mm x D2.8mm; 214g) (7 3/4" x 2 3/4"x 11/8" 0.47pounds) Stimulates the ear with quiet sounds. Non-invasive, records physiological responses to these sounds. Automatically evaluates the evidence for a response. Reports a concise result output about the presence or absence of normal responses. Saves a detailed record of the test. Device alerts to the possibility of hearing loss and documents the status of the ear.	Handheld device (L280mm x W83mm x D45mm; 446g) (11" x 3 1/4" x 13/4" **1** pound) Stimulates the ear with quiet sounds. Non-invasive, records physiological responses to these sounds. Automatically evaluates the evidence for a response. Reports a concise result output about the presence or absence of normal responses. Saves a detailed record of the test. Device alerts to the possibility of hearing loss and documents the status of the ear.	Otoport Pro is smaller and lighter. The predicate Otoport OAE+ABR was heavier and larger because it incorporated an adaptor 'shell', fitted over the basic Otoport OAE product, to provide AABR functionality. In the Otoport Pro subject device, the AABR functionality has been built into the basic handheld device as the attachment of an ABR adaptor shell is not required.
Device Components/ Features	Stimulates the ear with either transient or tonal sounds via an inserted earpiece	Stimulates the ear with either transient or tonal sounds via an inserted earpiece	Same
	Registers interfering acoustic noise and advises users when this is too large for testing to take place.	Registers interfering acoustic noise and advises users when this is too large for testing to take place.	Same
	Implements otoacoustic emission technology to record TEOAE and DPOAEs responses to sound applied via an inserted earpiece (probe)	Implements otoacoustic emission technology to record TEOAE and DPOAEs responses to sound applied via an inserted earpiece (probe)	Same
	Provides an intensity and frequency analysis of the OAE response, numerically and graphically	Provides an intensity and frequency analysis of the OAE response, numerically and graphically	Same
	Automatically determines and displays the presence or absence of a normal TEOAE or DPOAE response	Automatically determines and displays the presence or absence of a normal TEOAE or DPOAE response	Same
	Implements auditory brainstem response (ABR) technology to record electro physiological responses via surface electrodes	Implements auditory brainstem response (ABR) technology to record electro physiological responses via surface electrodes	Same
	Stimulates the ear for ABR screening at 30,35,40, or 45dBnHL (60dBHL for training)	Stimulates the ear for ABR screening at 30,35,40, or 45dBnHL (60dBHL for training)	Same
	Registers interfering electrical noise and advises users when this is too large for testing to take place.	Registers interfering electrical noise and advises users when this is too large for testing to take place.	Same
	Registers the electrical impedance of electrode connections to the patient and advises users when this is too large for testing to take place	Registers the electrical impedance of electrode connections to the patient and advises users when this is too large for testing to take place	Same
	Performs statistical analysis on the ABR response to decide if it is present and normal	Performs statistical analysis on the ABR response to decide if it is present and normal	Same
	Automatically determines and displays the presence or absence of a normal ABR response	Automatically determines and displays the presence or absence of a normal ABR response	Same
	Serves as a hearing based on the presence or absence of a normal OAE or ABR response	Serves as a hearing based on the presence or absence of a normal OAE or ABR response	Same

Population	Infant and adult (Infant only for AABR)	Infant and adult (Infant only for AABR)	Same
Intended user	Trained operators for screening, and professionals for screening and clinical use	Trained operators for screening, and professionals for screening and clinical use	Same
Safety characteristics	Electrically isolated from any device connected to its UCB-C charging and data connector. Acoustic stimulation levels physically constrained and monitored with active protection against single faults.	Electrically isolated from any device connector to its Hirose charging and data connector. Acoustic stimulation levels physically constrained and monitored with active protection against single faults.	Same
Enclosure material	The device enclosure materials are Polylac PA-765 Flame retardant ABS. Injection moulding.	The device enclosure materials are Polylac PA-765 Flame retardant ABS. Injection moulding.	Same materials. Comply with the current biocompatibility standards.
Materials of Construction	Probe: plastic encapsulated insert earphone containing microphone and receiver, fitted with disposable single use plastic tip	Probe: plastic encapsulated insert earphone containing microphone and receiver, fitted with disposable single use plastic tip	Same
	For ABR screening - Surface, self-adhesive skin electrodes. Electrode cables: PVC (Biocompatible)	For ABR screening - Surface, self-adhesive skin electrodes Electrode cables: PVC; Nylon (Biocompatible)	Same materials. Comply with the biocompatibility standards.
	Electronic circuitry providing stimulation drive to the probe, amplification for the signals, received from the probe microphone and electrodes, signal processing for response enhancement and noise rejection, microprocessor for signal and statistical analysis, all encapsulated in a plastic housing, including graphic display unit and data input facilities plus rechargeable battery.	Electronic circuitry providing stimulation drive to the probe, amplification for the signals, received from the probe microphone and electrodes, signal processing for response enhancement and noise rejection, microprocessor for signal and statistical analysis, all encapsulated in a plastic housing, including graphic display unit and data input facilities plus rechargeable battery.	Similar. Individual circuit components have been changed to avoid obsolescence with equivalent or superior performance items.
Sterile	No	No	Same
Duration of placement	Less than 5 minutes per ear	Less than 5 minutes per ear	Same
Usage of patient contact items	Acoustic probe tip and electrodes are single patient use only	Acoustic probe tip and electrodes are single patient use only	Same
Anatomical placement	Scalp, forehead, nape, shoulder	Scalp, forehead, nape, shoulder	Same
Number of Electrodes	3	3	Same
Electrode Sockets	Yellow, Touchproof Connector, SSB, 4-pin, 1mm. PVC. Biocompatible	DIN 42-802 Type ST 'Touchproof' terminated electrode cables. Electrode cable connectors Nylon: ZYTEL 70G33L. Biocompatible	Similar The same Plastics One manufacturer of the connector. Both types are for EEG cables/ electrodes. Otoport Pro has all 3 electrode cables in one single connector.

			Otoport ABR predicate has individual connectors for each of the 3 electrode cables. The connectors for both Otoport Pro and predicate Otoport ABR are biocompatible and substantially equivalent in functionality and performance.
Battery	Lithium-ion Battery	Lithium-ion Battery	same
Battery voltage operating range:	3.2-4.2V	3.2-4.2V	same
Source	Source: l000mAh lithium polymer internal rechargeable cells	Source: l000mAh lithium polymer internal rechargeable cells	same
Electrode Cable	Gray, Tinsel Wire, 3 x 0.023 conductor, Shielded, 0.120 Dia. PVC jacket. Biocompatible.	Electrode Cable Insulations: PVC, Mexichem 2235L-75. Biocompatible.	Similar. The Otoport Pro cable has all 3 electrode cables inside one shield and also ground shielding on most of the length. The Otoport Pro electrode cables with single connector to device run to 3 cable ends-electrode connections to patient (same with Otoport ABR). Otoport ABR electrode cables are 3 individual electrode cables running from device to patient. The electrode cables for both Otoport Pro and predicate Otoport ABR are biocompatible and substantially equivalent in functionality and performance.
Probe Connector	Two (14 pin) 'Medi-Snap' connector push pull connector	'Triad' (8 pin) connector metal collar to screw lock in place. Binaural option has two such probe connectors	Similar. The probe connector for the subject device is a 14 pin "Medi-Snap" connector while the predicate device uses an 8 pin "Triad" connector. The Otoport Pro probes are substantially equivalent with legacy probes of predicate Otoport ABR, which have been in service for 20+years. The only difference is the connectors. The 14 pin Medi-Snap connector of the Otoport Pro serves the same purpose as the predicate, but it's insertion and removal are mechanically different. Instead of a screwed collar locking method, the Medi-Snap features a Push-in/Pull-out mechanism with adequate retention when in.

			This provides an easier user experience and reduces risk of connector damage by mishandling. Connector damage would be detected by recommended QA tests. The Mini-Snap further improves safety by not exposing metal parts to user. The residual user risks remain low/ are acceptable.
Probes	UPS, UPD & XPD probes TEOAE/ DPOAE Functionality probes.	All models take UGS & UGD probes. Can also take the XGD probe with a firmware update. TEOAE/ DPOAE Functionality probes.	Similar. Substantially equivalent TEOAE/ DPOAE probes. The subject device is compatible with all the probe types useable with the predicate device when supplied with a Medi-Snap connector (UPS, UPD and XPD). Differences in the probe connectors to the device: Predicate has UGS/ UGD/ XGD probes with metallic screw connectors to the Otoport. Otoport Pro has UPS/UPD & XPD probes with plastic clip-on connectors to the device (easier to use).
Number of Probes Connected	The Otoport Pro can accept 2 probes	The Otoport OAE+ABR binaural option can accept 2 probes, otherwise only 1 probe	The subject and predicate base models (Otoport Pro and Otoport) are similar in that both can accept 2 probes for binaural recording. With the predicate 2 probes was only available with the binaural OAE+ABR variant. With the subject device, 2 probes capacity is standard.
Electrode Socket Connector	Otoport Pro has one 4 Pin Plug & Socket Connector	Three Single Pin Plug and Socket Connectors	The Otoport Pro and the predicate device are similar that they require 3 electrode connections to perform the ABR screening test. The Otoport Pro uses a single 4 pin plug and socket connector, while the predicate uses three single pin plug and socket connectors. The electrode cabling is different and incudes an EMC shield, which reduce interference noise. The 4-pin single electrode cable socket of the port Pro provides a

			simpler method of connection for the user and incorrect connections are eliminated. In the predicate incorrect connection was mitigated by clear color coding of the electrode cables and sockets. The single 4pin connection of the Otoport Pro affords less parts/ with easier use while the functionality remains the same and the residual user risks remain low/ are acceptable. Incorrect connection is not possible.
Charging and data transfer connector	USB-C for charging and download	Hirose proprietary connector for charging and download	Similar. Improved useability and reliability.
Device Components / Features	A handheld battery powered hearing screening device with integral keypad and display which shows processed real time data. OAE/ ABR Functionality.	A handheld battery powered hearing screening device with integral keypad and display which shows processed real time data. For the ABR functionality the ABR module attachment fitted on the Otoport is required. OAE/ ABR Functionality.	In the Otoport Pro ABR functionality is integral to the basic unit. No adaptor is needed to enable ABR screening functionality. This enhances usability and convenience- simplicity. Residual risks associated with ABR adaptor shell fitting are removed. The residual risks are found to be low/ are acceptable.
User Interface	The Otoport Pro preinstalled software provides complete user control over the testing hardware inside the Otoport Pro and displays test progress, test results, and tests saved in the in-built database. Optionally, Otoport Pro database contents can be securely transferred to Otodynamics Otolink software for review, printing, or archiving. Otoport Pro firmware can be securely updated from Otolink	The Otoport preinstalled software provides complete user control over the testing hardware inside the Otoport and displays test progress, test results, and tests saved in the in-built database. Optionally, Otoport database contents can be securely transferred to Otodynamics Otolink software for review, printing, or archiving. Otoport firmware can be securely updated from Otolink"	Similar. Products usability engineering compliance to current standards/ regulations/ acceptable.
Test data storage	Internal, encrypted searchable database with capacity for 1024 patients, 5000 test records, maximum 256 tests/patients	Internal, proprietary encoded searchable database with capacity 1000 patients, 5000 test records	similar

Data Transfer	Data transfer is via wired USBl.1 or 2.0 to third party computer running Otodynamics Otolink software. Otoport Pro has Bluetooth 5 functionality which can also be used to transfer data to Otolink. The USB connection is made by a USB C connector.	Data transfer is via wired USBl.1 or 2.0 to third party computer running Otodynamics Otolink software. Otoport OAE+ABR has Bluetooth 2.0 functionality can also be used to transfer data to Otolink.	Similar, both the subject and predicate have both Bluetooth capability for completed test data transfer; however, the Bluetooth 2 which is used on the predicate device is now obsolete and superseded by Bluetooth 5 which is used on the subject device. Data can also be transferred by wired USB cable as with the predicate. The use of a USB C connector instead of the predicate proprietary HiRose connector increases user convenience. Device safety benefits from total electrical isolation (onto isolation) between it and the attached device (PC or charger).
Barcode reader	Has optional 2D barcode scanner for patient ID and demographics inputs.	Has optional 1D barcode scanner for patent ID and demographics inputs.	Similar. The provision of the optional 2D barcode reader allows more patient data to be transferred to the device database and is also compatible with 2D barcoding which are still in widespread use.
Charging	Charging/ Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.lor 2.0) via Data Cable.	Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.lor 2.0) via Data Cable.	Similar, but now the subject device has total electrical isolation from any device connected to its USB-C port.
Power States	Intelligent multi-level power control for charging/testing/idle/sleep/shutdown	Intelligent multi-level power control for charging/testing/idle/sleep/shutdown	The same way of charging, testing, Idle mode, sleep, shutdown.
Charge Time	3.5 Hrs. to 100% for supplied PSU charge, 5 hours for PC charge	4 Hrs. to 100%	Similar
Max consumption when testing:	1W	1W (Otoport) or 1.3W (Otoport ABR)	Similar
Max consumption when charging:	2.65W when charging from USB connection. 3.5W when charging from supplied PSU.	2.5W	Similar. Consumption of the unit is 2.5W when charging battery from a USB to comply with USB standards. When charged with the supplied charger/PSU, charging is faster, and the consumption is 3.5W. This improvement in charge speed is possible because of the Otoport Pro's improved 5V isolator circuit.

TABLE 2. COMPARISON BETWEEN THE SUBJECT DEVICE AND THE PREDICATE – Stimulus Parameters

	Subject Device **Otoport Pro**	**Predicate Device** **Otoport/ Otocheck OAE+ABR (K143395)**	**Overview of similarities and differences**
	Transient Evoked Otoacoustic Emissions (TEOAE)		
Stimulus Levels	Idle - 80µs positive broadband square wave pulse with an intensity of 64dBpeSPL (peak equivalent) in a 1cc cavity. Adjusted 80µs positive broadband square wave. Testing - 300µs biphasic broadband triangular pulse; - Screening level: 84dBpeSPL-Clinical mode: adjustable in 2dB increments; Range 50-90dBpeSPL	Idle - 80µs positive broadband square wave pulse with an intensity of 64 dBpeSPL (peak equivalent) in a 1cc cavity. Adjusted 80µs positive broadband square wave. Testing - 300µs biphasic broadband triangular pulse; - Screening level: 84dBpeSPL-Clinical mode: adjustable in 2dB increments; Range: 50-90dBpeSPL	same
Sample rate	20kHz	20kHz	same
Stimulus pattern	Each sweep presents 8 stimuli responses with the stimulus presentation pattern: A A A B -A -A -A -B Where: B = -3A	Each sweep presents 8 stimuli responses with the stimulus presentation pattern: A A A B -A -A -A -B Where: B = -3A	same
Noise level calculation	The noise level for noise reject is calculated from the difference between alternate averaged sweeps	The noise level for noise reject is calculated from the difference between alternate averaged sweeps	same
Stimulus repetition rate	One stimulus every 13ms, approximately 80 stims per second	One stimulus every 13ms, approximately 80 stims per second	same
Response window	3-13ms or 3-9ms after start of stimulus presentation. Cosine filtered with rise and fall time of 2ms	3-13ms or 3-9ms after start of stimulus presentation. Cosine filtered with rise and fall time of 2ms	same
Response frequency bands	Half octave, centered at 1k, 1.4k, 2k, 2.8k, 4k and 5.6kHz	Half octave, centered at 1k, 1.4k, 2k, 2.8k, 4k and 5.6kHz	same
	Distortion Product Otoacoustic Emissions (DPOAE)		
Stimulus level	Preset L1:L2 60:50dBSPL; 65:55dBSPL; 70:60dBSPL For clinical measurement L1 and L2 adjustable Range 50-75dBSPL	Preset L1:L2 60:50dBSPL; 65:55dBSPL; 70:60dBSPL For clinical measurement L1 and L2 adjustable Range 50-75dBSPL	same
Sample rate	25.6kHz	25.6kHz	same

FFT frequency Bin	25Hz	25Hz	same
DP noise calculation	DP noise is calculated from the five spectral points above and the five points below the DP frequency. A margin of 1 or 2 standard deviations is applied for precise clinical measurements	DP noise is calculated from the five spectral points above and the five points below the DP frequency. A margin of 1 or 2 standard deviations is applied for precise clinical measurements	same
Stimulus frequencies (F2)	***1-6kHz, 1.5-8kHz, 2-6kHz (Recommended)*** 1.5-8k tests at six F2 frequencies: 1.5k, 2k, 3k, 4k, 6k and 8kHz 1-6k tests at six F2 frequencies: 1k, 1.5k, 2k, 3k, 4k and 6kHz 2-6k tests at four F2 frequencies: 2k, 3k, 4k and 6kHz Screening: half or quarter octaves between 1k and 8kHz Clinical measurement mode. Configurable start/stop frequencies up within device resolution. Up to 16 frequency points per sweep, between 1k and 8kHz	***1-6kHz, 1.5-8kHz, 2-6kHz (Recommended)*** 1.5-8k tests at six F2 frequencies: 1.5k, 2k, 3k, 4k, 6k and 8kHz 1-6k tests at six F2 frequencies: 1k, 1.5k, 2k, 3k, 4k and 6kHz 2-6k tests at four F2 frequencies: 2k, 3k, 4k and 6kHz Screening: half or quarter octaves between 1k and 8kHz Clinical measurement mode. Configurable start/stop frequencies up within device resolution. Up to 16 frequency points per sweep, between 1k and 8kHz	same
Frequency ratio f2/f1	1.22	1.22	same
	Automated Auditory Brainstem Response (AABR)		
Stimulus levels	For infant screening only; 35 or 40dBHL are recommended. (A higher level up to 60dBHL is provided for the training of adult screeners)	For infant screening only; 35 or 40dBHL are recommended. (A higher level up to 60dBHL is provided for the training of adult screeners)	same
Stimulus rate	51.8-57.9/second, alternating polarity.	51.8-57.9/second, alternating polarity.	same
Stimulus type	Chirp (default recommended) or click	Chirp (default recommended) or click	same
Sampling rate	25.6kHz	25.6kHz	same
Capture time frame	17.3 to 18.8ms	17.3 to 18.8ms	same
Capture bandwidth	150-1000Hz	150-1000Hz	same
Evaluation method	Fsp with infant template matching	Fsp with infant template matching	same
Electrode Impedance sensing	400Hz. Less than 5microamps - to over 16kohms	400Hz. Less than 5microamps - to over 16kohms	same
Amplifier	Differential, 75dB CMR>60dB@100Hz, 1Mohm. Dynamic powerline rejection.	Differential, 75dB CMR>60dB@100Hz, 1Mohm. Dynamic powerline rejection.	same

Non-Clinical Performance Testing

Electrical safety and electromagnetic compatibility (EMC)

Both electrical safety and EMC testing have been conducted on the Otoport Pro Device. The system complies with ANSI/AAMI/IEC ES60601-1:2005/(R)2012 and AI:2012 for basic safety and essential performance of medical electrical equipment.

The electromagnetic compatibility of the system has been confirmed through third-party testing to collateral standard IEC 60601-1-2 Edition 4.0 2014-02.

Software Verification and Validation Testing

Software verification and validation testing has been conducted in compliance with IEC 62304 Edition 1.1 2015-06 (which is the principal normative standard applied), ANSI/AAMI/IEC ES60601-1:2005/(R)2012 and AI:2012 and the FDA guidance documents "General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (11-Jan-2002) and "FDA Guidance for the Content of Premarket Submissions for Device Software Functions" (14-June-2023).

Cybersecurity

Issues regarding cybersecurity are included for resolution at all appropriate phases of the products development process. Cybersecurity is addressed in the Software Risk Analysis and risk mitigation measures against cybersecurity risks are incorporated into the software requirements specifications. The Otodynamics products/ services considered and followed the recommendations in “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and Food and Drug Administration Staff (27-September- 2023)” and current medical devices cybersecurity regulations.

The hardware and firmware changes do not negatively affect the cybersecurity, safety, reliability, usability, and longevity of service of the device relative to the predicate.

Clinical Performance Testing

The indications of use of the Otoport Pro are the same as for the predicate device Otoport OAE+ABR.

The performance of each test modality of the Otoport Pro has been demonstrated to be similar to that of the predicate Otoport OAE+ABR in bench tests and in a clinical measurement trial.

Measurements of the acoustic stimulus and recorded auditory response

1. Measurement by a calibrated microphone of the amplitude and waveform of the acoustic stimulus delivered into a calibrated ear simulator after level setting by the Otoport Pro and Otoport OAE+ABR, in TEOAE, DPOAE and AABR testing modes, using the same probe on each device.
2. Measurement by the device of the response recorded by both Otoport Pro and Otoport OAE+ABR in TEOAE, DPOAE and AABR testing modes, when presented with an electronically generated derived/triggered from the device’s acoustic stimulus (i.e., simulated) TEOAE, DPOAE or ABR response signal respectively.

<u>The acoustic stimulus differences between the devices (using the same probe) were</u>
TEOAE differences were less than 0.4dB,
DPOAE an average difference of less than 0.3dB form 1-8kHz, with a maximum deviation of 0.8dB, and
AABR an average difference of 0.2dB from 2-4.5kHz

<u>The received response differences</u>
TEOAE average of 0.23 dBSPL,
DPOAE average difference 0.4dB, with largest differences less than 2dB, and
AABR average difference 0.1dB

Clinical measurement comparison

AABR, TEOAE and DPOAE measurements were made on a cohort of adult volunteers giving informed consent, using both the Otoport Pro and the predicate Otoport OAE+ABR, using the same probe which remained in position for each comparison. Tests were conducted in a sound booth by a qualified audiologist.

Screening mode (default for newborns)
TEOAE screening was performed with a click stimulus at level 84dBSPLpe, with 6dBSNR pass criteria in 2 half octave bands;
TEOAE screening of 17 subjects tested for TEOAE, 15 passed on both instruments, the same 2 failed on both instruments.

DPOAE screening was performed at stimulus levels of L1 65 dBSPL and L2 55 dBSPL for f1 and f2 tones at half octave intervals from 1.5 to 6kHz;
DPOAE screening of 16 subjects tested for DPOAE, 13 subjects passed the default (newborn) screening criteria on both instruments, 3 failed on both instruments, and these subjects failed at the same frequency on each instrument.

AABR screening was performance with a chirp of 40dBHL - audiologically calibrated on 25 healthy young adults;
AABR of 14 subjects tested for ABR, 12 subjects passed on both instruments, the same 2 subjects failed on both instruments (with no clear response and high EEG).

Test times were similar on both instruments at about 100 seconds. Average pass ABR amplitudes were 0.49 µV for the Otoport Pro and 0.51 µV for the predicate. This difference is not significant. Both devices reported the same electrode impedances within 240 ohms.

Clinical (measurement) mode
TEOAE: the TEOAE level in half octave bands were measured from 1k to 6kHz. The difference between the mean TEOAE levels reported by the two devices was less than 1dB at each half octave frequency.
DPOAE: 13-point DPgrams were recorded on both devices, using the same probe. Levels of L1=L2 of 70 dBSPL were chosen for this older subject cohort, as this might be used clinically to measure DPOAE strength.
Averaged across 15 subjects, the mean DPOAE level difference was less than 1dB at each frequency (1k-8kHz). This difference in DPOAE levels between instrument is not audiologically significant.

AABR - no clinical /diagnostic ABR facilities are available on the Otoport Pro.

CONCLUSIONS

The Otoport Pro Device has the same intended use as the predicate device.

The Otoport Pro is substantially equivalent to the Otoport/Otocheck OAE+ABR predicate device with respect to overall device design elements and features. Functional bench testing supported the electronic and acoustic equivalence of the subject and predicate devices. The non-clinical testing has supported the safety and functionality of the device and the indications for use whilst the performance testing data demonstrates that the device is substantially equivalent to the predicate.