June 21, 2024

Otodynamics
℅ Chandler Thames
Quality/Regulatory Consultant
Rook Quality Systems
1155 Mount Vernon Hwy
Suite 800
Dunwoody, Georgia 30338

Re: K234095
Trade/Device Name: OtoNova/OtoNova Pro
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: May 21, 2024
Received: May 21, 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.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234095

Device Name
OtoNova/OtoNova Pro

Indications for Use *(Describe)*
This Otonova 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 9 April.2024

DEVICE

Trade Name:	OtoNova/OtoNova Pro
Common Name:	OtoNova/OtoNova Pro
Classification Name:	Audiometer / Evoked response auditory stimulator (874.1050 & 882.1900)
Regulatory 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.

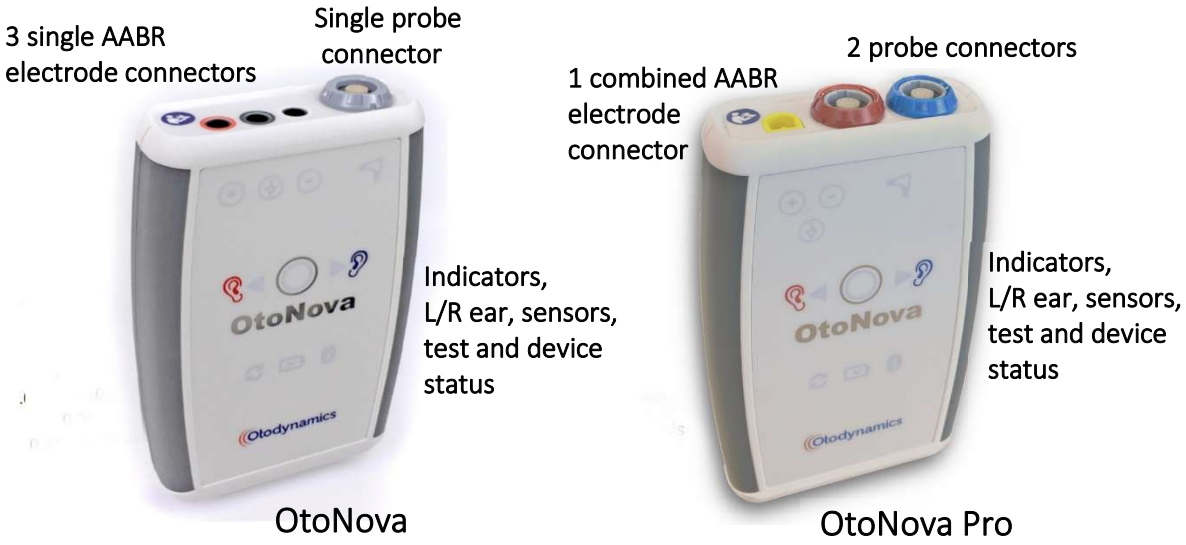
This predicate has not been the subject of any design-related recalls.

DEVICE DESCRIPTION

OtoNova is a compact, portable battery-powered electronic device which records physiological responses to sound for the purpose of hearing testing. It Is controlled wirelessly from a local controlling device.

OtoNova has two hardware variants: OtoNova and OtoNova Pro, illustrated below in Figure 1.

FIGURE 1

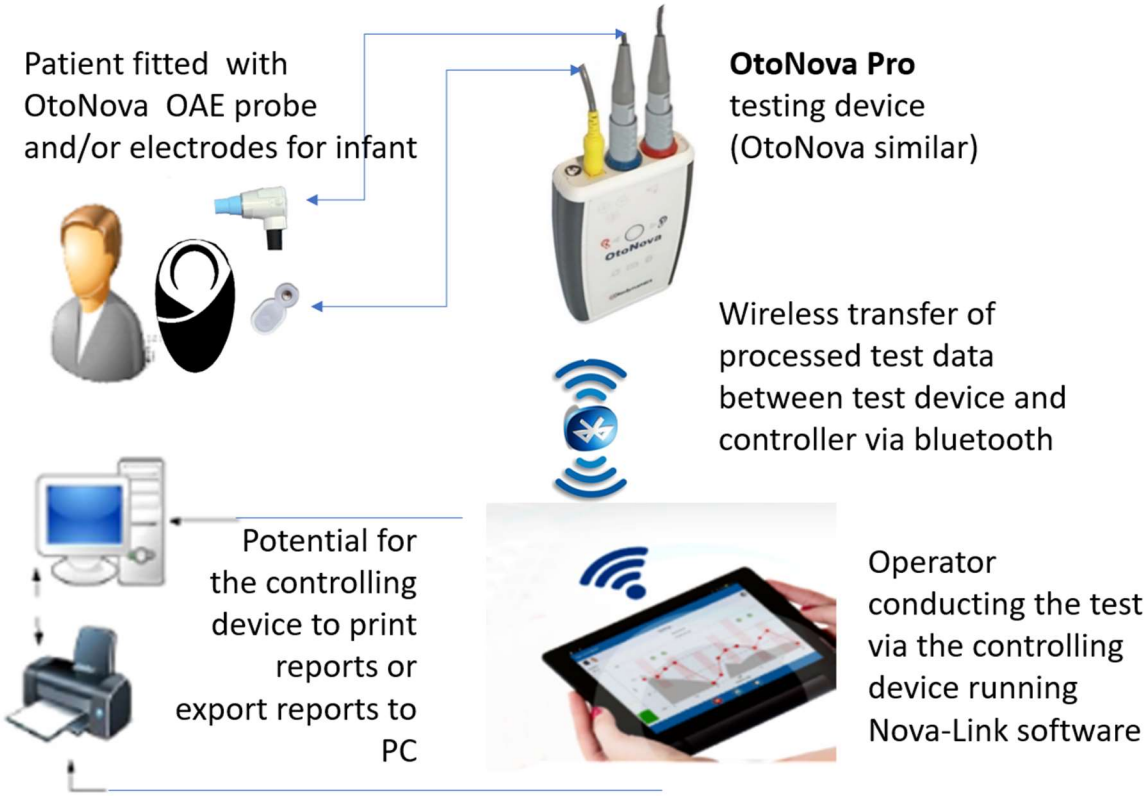


- OtoNova (left) has 3 separate connectors for 3 ABR electrode connections and accepts one probe. The OtoNova Pro (right) has a combined electrode connector and accepts 2 probes (red and blue sockets).

- The OtoNova and OtoNova Pro perform the same audiological tests. The devices are controlled wirelessly from a separate controlling device. This can be a PC, a laptop or Android tablet running the supplied 'Nova-Link' software.

Figure 2 illustrates the configuration of OtoNova Pro in use. The test operator commands the OtoNova Pro from the supplied Nova-Link application running on the controlling device. OtoNova operates in the same way.

Figure 2. Operation of the OtoNova with Nova-Link



Both the OtoNova and OtoNova Pro devices have been directly engineered from Otodynamics' currently marketed Otoport OAE+ABR device, retaining all the testing algorithms of the Otoport OAE+ABR device. The primary aim of the development was to physically separate the control console from the testing device while maintaining the same performance and effectiveness.

Separation of testing and controlling devices provides several advantages to the user. It gives greater freedom for the relative positioning of patient and tester within the test environment. This may be advantageous when testing infants, children, or when testing a patient from outside of a test booth. It also provides choice of controlling processor and display. For example, a tablet allows the operator to observe tests and records on a full size display screen, rather than on a diminutive handheld device screen. It also allows access other services on the controlling device.

Principles of operation

Like the predicate Otoport OAE+ABR device, both OtoNova devices can record two different physiological indicators of a functioning auditory system's peripheral response to sound namely
a) Otoacoustic emission (OAEs), which are small sounds made by the inner ear in response to acoustic stimulation, and b) Auditory brainstem responses (ABRs) are tiny electrical signals emanating from the auditory brainstem in response to sound. Automatic recognition of an ABR response is referred to as AABR.

During ABR or OAE testing, low-level sounds are delivered to the ear. The responses to multiple presentations of these sounds (either acoustic or electrical responses) are recorded digitally and added together to enhance repeated responses with respect to the random/ noise signals that are always present. The averaged signal is automatically analysed by the device to identify and quantify true physiological response component and to assess the degree of noise contamination. This allows the quality/ accuracy of the recording to be determined for evidence of response validity. The processed data is reported to and displayed on the controlling device.

Impaired/ defective ears do not produce a response which meets the pass criteria of the device. The pass criteria of the OtoNova are the same as those of the predicate Otoport device. In SCREENING applications all failures to record a clear response which are not attributable to technical issues (e.g., an excess of noise or insufficient test duration) are recommended to be referred for further audiological investigations to determine if there is a hearing problem. Both serious and trivial ear problems (e.g., a blocked ear canal) can prevent the criteria being met and so cause a test failure. Technically inadequate recordings are recommended to be repeated after addressing the technical issues.

In CLINICAL OAE applications the strength of the OAE response is measured at differing stimulus frequencies and stimulus levels. The analysis is intended to be used as one input to a diagnostic process in conjunction with other audiometric tests, or as a means of monitoring cochlea status over time.

Both OAE and ABR responses are acoustically stimulated. The stimulus is delivered to the ear by an inserted earphone device called a 'probe'. The probe contains a microphone which also records the OAE response, and the acoustic stimulus given.
Figure 3 shows compatible Otodynamics probes intended for stimulation and recording of DPOAE, TEOAEs, and for both TEOAEs and DPOAE. These are the UPD, UPS and XPD probes respectively.

Figure 3 Otodynamics probes

The ABR response can be acoustically stimulated by any one of these probes but it is recorded electrically via 3 disposable self-adhesive conducting pads called 'electrodes', which are placed on the scalp (Fig 4).

Figure 4 Otodynamics Electrodes (AABR testing)

For ABR stimulation the probe may be inserted into the ear canal (as for OAEs) or into a plastic cushioned

'ear cup' which is placed over the ear. ABRs recording with OtoNova are intended for infant screening only.

Both OtoNova and OtoNovaPro variants offer the same two modes of hearing function assessment, that is OAE and AABR, separately or in combination, with optional levels of utilities.

The hearing test functions available on a device are identified by 6 OtoNova model names as follows:

- OtoNova OAE,
- OtoNova AABR,
- OtoNova OAE+AABR

- OtoNova Pro OAE,
- OtoNova Pro AABR,
- OtoNova Pro OAE+ABR

The level of utilities available is further determined by the Nova-Link program and the installed application package. There are three variants of Nova-Link application levels:
SCREENER, CLINICAL and ADVANCED CLINICAL.
These are available on both standard OtoNova and OtoNova Pro.

SCREENER LEVEL functionality provides Basic OAE and or AABR screening with preset automated pass/refer test protocols.
CLINICAL LEVEL provides all of the SCREENING LEVEL functionality plus detailed OAE analysis over a selectable frequency range at configurable stimulus levels. If AABR is enabled, examination of the ABR screening waveform and test conditions are available. No ABR diagnostic information is provided.
ADVANCED CLINICAL LEVEL functionality provides the same screening and clinical tests with enhanced user protocol definitions.

INDICATIONS FOR USE

The OtoNova 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 for screening 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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

The OtoNova reproduces the Otoport/Otocheck OAE+ABR predicate device with regard to its acoustic stimulation, response gathering, analysis, display, and report generation database capabilities. The OtoNova has the same intended uses and fulfills the same roles as the predicate device.

Basis of the screening functions of the OtoNova and OtoONova Pro

The OAE and ABR screening functions of the OtoNova and OtoNova Pro are identical to the Otoport OAE+ABR predicate device (K143395).

The OAE infant screening function of OtoNova (subject) and Otoport (predicate), via its stimulus levels and pass criteria is as developed and verified in the Rhode Island Hearing Screening Assessment Project and reported in "The Rhode Island Hearing Assessment Project:Implications for universal newborn hearing screening. Seminars in Hearing 1993, Volume 14 Number 1. ". That algorithm now in use on the OtoNova requires a response to a nonlinear transient stimulus at 84dBSPL peak equivalent level, of 6dB or more greater than the measured noise level (ie signal to noise level) in at least two half octave frequency bands between 1 and 4kHz.

The ABR infant screening function of the OtoNova presents a short chirp stimuli at 35dBHL or 40dBHL, and an requires a response waveform with a standard Fsp statistic of at least 3.1 (elevated according to noise levels) in addition to a waveform match to a newborn ABR template.

The stimulus level of the short chirp provided by the Otonova is automatically adjusted to the recommended dBHL sound level according to our measurements of hearing threshold of this stimulus in 25 healthy young adults with no hearing problems, using the Otoport and Otodynamics probe.

The newborn ABR template used as in integral part of the pass criteria of the OtoNova and Otoport devices was derived from a database 1000 infant's ABR screening response waveforms independently collected using the Otodynamics ILO88 instrument (K962995) as part of the a multicenter investigation into the Identification of Neonatal Hearing Impairment as reported in " Identification of Neonatal Hearing Impairment: Summary and Recommendations Norton, Susan J.; Gorga, Michael P.; Widen, Judith E.; Folsom, Richard C.; Sininger, Yvonne; Cone-Wesson, Barbara; Vohr, Betty R.; Fletcher, Kristin A. Ear and Hearing 21(5):p 529-535, October 2000.

The complete ABR infant screening algorithm of the Otoport OAE+ABR device - now duplicated in the OtoNova- was validated on 70 infants performed at Otodynamics Ltd and was then independently trialled in collaborating hospitals in USA, Brazil, Israel and UK . The algorithm was validated from 1078 tests files and results provided by these trials. Separately and independently the performance of the Otoport OAE+ABR screening function was evaluated on 56 neonates at a UK hospital by direct comparison with a Natus ABR screening product.

Table 1 Equivalence Table.

	Subject Device OtoNova/OtoNova Pro	Predicate Device Otoport/Otocheck OAE+ABR (K143395)	Discussion
Common Name	Audiometer Evoked response auditory stimulator.	Audiometer Evoked response auditory stimulator	same
Regulaton Numbers	Audiometer 21 CFR 874.1050, Evoked response auditory stimulator 21 CFR 882.1900	Audiometer 21 CFR 874.1050, Evoked response auditory stimulator 21 CFR 882.1900	same
Classification Product Codes	II	II	same
Product Codes	EWO & GWJ	EWO & GWJ	same
Intended Use	For use in the detection hearing disorders in infants with AABR or OAEs, B8and to provide objective input from OAEs for use as part of a diagnostic audiological test battery with infants children and adults.	For use in the detection hearing disorders in infants with AABR or OAEs, and to provide objective input from OAEs for use as part of a diagnostic audiological test battery with infants children and adults.	same
Indications for Use	This Otonova 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. In all other cases the user should be an audiologist or medical professional. The device is also indicated when objective non-invasive clinical investigations require the characterization and monitoring of the functional status of the peripheral auditory function using otoacoustic emissions (OAEs). It may also be used in populations of any age to obtain objective evidence of normal peripheral auditory function.	Similar. The OtoNova and OtoNova Pro manuals explicitly name the OAE's used.

Overall Device Design	Portable device (120mm x 79mm x 26mm; 170g) Stimulates the ear with quiet sounds. Non-invasive, records physiological responses to these sounds. Automatically evaluates the evidence for a response Transmitsprocessed results by bluetooth wireless connection to the controling device (tablet). Controlling device displays a concise results about the presence or absence of responses Saves a detailed record of the test on the controlling device As a screener the device alerts to the possibility of hearing loss and in clinical use documents the status of the ear by OAEs	Handheld device (197mm x 70mm x 30mm; 250g) Stimulates the ear with quiet sounds. Non-invasive, records physiological responses to these sounds. Automatically evaluates the evidence for a response Displays a concise results about the presence or absence responses on its integral display. Saves a detailed record of the test Device alerts to the possibility of hearing loss and documents the status of the ear	Similar. The only significant differences between device designs is that in the OtoNova there is a separation of testing device from controlling device via a bluetooth wireless link.The subject device is of lighter weight and smaller body. It is to be marketed as portable for use a controling device which runs the supplied Nova-Link software. The predicate is a self contained handheld device with its own diplay screen and keypad, making it heavier and larger.
User Controls	Via touch screen or keyboard of the controlling device running the supplied Nova-Link software which wirelessly commands the OtoNova test device	Via soft keypad on the handheld device	Equivalent.The OtoNova's 'Nova-Link' software provides the same control functions via touch screen or keyboard of the controlling device, as does the Otoport OAE+ABR device via its keypad.D13
Test Specifications	ABR Stimulus for infant screening Chirp 30-45dBnHL . 35 & 40dBnHL, recommended. 60dBnHL available as a training aid only , not for screening DPOAEs.Frequency ratio F2/F1 1.22. F2 frequency range 1-8kHz , Stimulus levels for screening L1/L2 preset 65/55, 60/55 or 65/50dBSPL Stimulus levels ofr clinical use L1 & L2 configurable 40-75dBSPL TEOAE Half octave analysis. Frequency range 1-6kHz Stimulus levels for screening 84dBSPLpe Stimulus levels for clinical use configurable 74- 84dBSPLpe, Advanced clinical 60-90dBSPLpe	ABR Stimulus for infant screening Chirp 30-45dBnHL, 35&40dB recommended. 60dBnHL available as a training aid only,not for screening DPOAEs.Frequency ratio F2/F1 1.22. F2 frequency range 1-8kHz , Stimulus levels for DP screening L1/L2 65/55dBSPL (confgurable) Stimulus levels ofr clinical use L1 & L2 configurable 40-75dBSPL TEOAE Half octave analysis. Frequency range 1-6kHz Stimulus levels for screening 84dBSPLpe recommended, configurable 60-84dBSPLpe Stimulus levels for clinical use configurable 60-84dBSPLpe	Similar. The OtoNova stimulus frequccny range s are the same as the predicate device. Both predicate and subject devices cover the most commonly used and validate stimlus levels . The OtoNova screening settings do not provide stimulus levels no longer judged appropriate for screening, but these are available on the clinical mode.
Automatic screening decisions	In screening mode OtoNova automaticaly provides an on screen 'Pass, Refer or invalid test result', plus indications of the reason for test invalidity.	In screening mode Otoport OAE+ABR automaticaly provides an on screen 'Pass, Refer or invalid test' result, plus indications of the reason for test invalidity.	Same
Stimulus calibration	with inserted probe - In-the-ear self calibration For AABR with ear-cup, stimulus is preset to dial level.	with inserted probe - In-the-ear self calibration For AABR with ear-cup, stimulus is preset to dial level.	Same

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.	
	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)	
	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	
	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	
	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	
	Stimulates the ear for ABR screening at 30,35,40,or 45dBnHL	Stimulates the ear for ABR screening at 30,35,40,or 45dBnHL	
	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.	
	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	
	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	
	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	
	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	
Population	OAEs Infant, child and adult, AABR, infant	OAEs Infant and adult, AABR, infant	Same
Intended user	Trained screener and professionals	Trained screener and professionals	Same
Safety characteristics	Electrically isolated. Acoustic stimulation levels physically constrained and monitored with active protection against single faults.	Electrically isolated. Acoustic stimulation levels physically constrained and monitored with active protection against single faults.	Same
Materials of Construction	Probe: plastic encapsulated insert earphone containing microphone and receiver, fitted with disposable single use plastic tip both as used with the predicate.	Probe: plastic encapsulated insert earphone containing microphone and receiver, fitted with disposable single use plastic tip	Same
	Surface, disposable self-adhesive skin electrodes	Surface, disposable self-adhesive skin electrodes	Same
	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 and microprocessor for signal and statistical analysis, rechargeable battery, m=power managment, LEDs to indicate states, bluetooth communication modules for reception of commands form the conrolling computer and the transmission of processed test data to the conrolling devce all encapsulated in a plastic housing,	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 and microprocessor for signal and statistical analysis, rechargeable battery, power managment, graphic display unit and data input keypad, and bluetooth module for tramission of test data to third party computer all encapsulated in a plastic	Similar. All devices have similar circuits and firmware providing the testing functions. The differences are that in the subject device bluetooth communication is two way and is updated during testing, whereas it is one way in the predicate device and it post test. Also the subject device hardware does not include a data input keypad or a graphic display as this is provided by the controlling device.D37
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 as used on the predicate device	Acoustic probe tip and electrodes are single patient use only	same

Electrode, number and Anatomical placement	Scalp, forehead, nape, shoulder	Scalp, forehead, nape, shoulder	same
Number of Electrodes	3	3	same
Electrode Socket Connector	OtoNova: Three Single Pin electrode Socket Connectors, compatible with DIN 42-802 Type ST 'Touchproof' terminated electrode cables OtoNova Pro: One 4 Pin Plug & Sock+B34et Connector and is compatiblel with the supplied combined electrode cable.	Otoport OAE+ABR has three Single Pin electrode Socket Connectors, compatible with DIN 42-802 Type ST 'Touchproof' terminated electrode cables	Similar. The OtoNova and the predicate device are similar in their use of three single electrode pin plugs and socket connectors.The exact same electrode cables and electrodes are used in OtoNova and predicate Otoport ABR. The OtoNova Pro uses a 4 pin plug and socket connector- combining 3 electrode connections and an electrical interference screen. The 4 pin single electrode cable socket of the OtoNova Pro provides a simpler method of connection for the user and incorrect connections are eliminated. In the OtoNova basic version incorrect electrode wires montage is mitigated by clear color coding of the electrode cables and sockets. This change in connector on OtoNova Pro affords less parts/ with easier use while the functionality remains the same and the residual user risks remain low/ are acceptable.D42
Battery	Lithium-ion Battery	Lithium-ion Battery	Same
Battery voltage operating range:	3.2-4.2V	3.2-4.2V	Same
Source	Source: 1000mAh lithium polymer internal rechargeable cells	Source: 1000mAh lithium polymer internal rechargeable cells	Same
Electrode Cable	OtoNova: compatible with DIN 42-802 Type ST 'Touchproof' terminated electrode cables - with snap electrode connectors. OtoNova Pro: Supplied 3 electrode combination cable with snap connectors	compatible with DIN 42-802 Type ST 'Touchproof' terminated electrode cables with snap elelctroc connectors	OtoNova:Same OtoNova Pro:similar, with the added simplicity of a single connection for the 3 electrodes

Probe Connector	(14 pin) 'Medi-Snap' connector push pull connector	(8 pin) 'Triad' connector metal collar to screw lock in place	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 addition 8 pins of the Medi-Snap connector are note currently used. The OtoNova / OtoNova Pro UPD and UPS probes are equivalent with legacy probes of predicate Otoport OAE+ABR which have been in service for 20+years. The only difference is the connectors. The Medi-Snap probe connector of the OtoNova serves the same purpose is the Triad connector of the preducate but its 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 pin damage by mishandling. Connector damage
Probes	OtoNova and OtoNova Pro accept UPS, UPD probes OtoNova Pro is additionally compatible with Otodynamics XPD probes and can accept two probes. All compatable probes include a chip containing calibration data.	Otoport OAE+ABR accepts UGS, UGD, and XGD probes All compatable probes include a chip containing calibration data.	Similar. The OtoNova Pro is compatible with all Otodynamics probes which the predicate Otoport devices are compatible if fitted with a Medi-Snap connector or via a connector adaptor. OtoNova (not pro) does not recognise the XPD probe because it has a differently structured calibration chip OtoNova and OtoNova Pro probes have a different 'push pull' connector than predicate Otoport probes but are acoustically and mechanically identicaly. This connector difference is indicated by the 'P' in their name eg
Number of Probes Connected	OtoNova - 1 probe OtoNova Pro 2 probes	The Otoport OAE+ABR can operate with one probe or two probes with the binaural option	The subject and predicate base models (OtoNova and Otoport) are similar while the OtoNova Pro and Otoport OAE+ABR can similarly accept two probes
Device Components / Features	A handheld battery powered hearing screening device which is wirelessly controlled (Bluetooth) by an Android or Windows PC device to display and communicate processed real time data.	A handheld battery powered hearing screening device with integral keypad and display which shows processed real time data	Similar. The OtoNova controlling processor provides all the functionality of the Otoport interface, but on a larger screen with the convenience of touch screen function. The wireless connection between the OtoNova controller device runniong Nova-Link software and the OtoNova test hardware gives greater freedom to the operator, better positioning themselves relative to the patient. The residual users risks are found to be low/ are acceptable.

User Interface	The OtoNova's 'Novalink' software runs on the selected controlling device and provides complete user control over the OtoNova testing hardware. Nova-Link displays test progress, test results, and saves tests in the in-built database. Optionally, Novalink database contents can be securely transferred to Otodynamics Otolink software for review, printing or archiving. Novalink is installed from Google play for Android devices or from Microsoft Store for PC devices"	The Otoport preinstalled software provide 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. There are no significant functional differences for the user between the OtoNova control program Nova-Link and Otoport built in control software. Differences are cosmetic, and ergonomic - resulting form the larger display screen, touch screen controll and large storage capacity because of access to the controlling device processor and memory
Data Transfer	OtoNova and OtoNova Pro test devices transfer processed test data to the third party controlling computer device wirelessly via bluetooth (4.2) as the test progresses. The controlling devide also commands the test device via bluetooth.	Otoport OAE+ABR can transfer completed and saved test records to a third party computer either wirelessly via bluetooth (2.0), or via a wired USB1.1 or 2.0 connection	Similar. The subject and predicate both use Bluetooth to tranfer processed test data between test and computer devices. Whereas the predication only transfered completed and files test records, the subject device uses bluetooth to command the testing device as well as to recieve processed test results from the test device as testing progresses. Bluetooth 4.2 is more robust than bluetooth 2. The OtoNova devices do not have a USB port. The controling device will have USB which can be used to securely transfer filed test records to a PC.
Charging	compatible with wireless chargers (transmitters) meeting WPC Qi standard v1.1 or v1.2	Charging is via a charging/data connector on the device - which connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1or 2.0) via a Data Cable.	Equivalent. The wireless charging of the OtoNova is advantageous because it requires no electrical connection of the device. This enhances its cleanability.
Power States	Intelligent multi-level power control for charging/testing/idle/sleep	Intelligent multi-level power control for charging/testing/idle/sleep/shutdown	Similar. The power states of OtoNova are identical to the Otoport except for the renaming of 'shutdown' (predicate) as Flight Mode (subject). When the subject sleeps detects physical movement and then actively searches for its host controller by bluetooth advertising information. For air transported this function must be disabled. The shutsdown state is named 'FlightMode' to make this clear. It is not necessary for the OtoNova to be toally powered down at any other time as the sleep mode can sustain operational battery charge for more than one month.
Charge Time	3.5 Hrs to 100%	4 Hrs to 100%	Similar . The subject device has a slightly shorter battery charging time at 3.5 hours versus the predicate device's 4 hours. This is advantageous for the user. The battery usage time of OtoNova is many times that of the predicate device because it does nothave to power a display screen.
Max consumption when testing:	0.5W	1W	Similar . The subject device uses less power than the predicate Otoport (0.5W vs 1W) because it is not powering an LCD display, which the predicate Otoport has.
Max consumption when charging:	2.5W	2.5W	Same

Summary of Non-Clinical testing

The OtoNova and OtoNova Pro use the same DSP firmware algorithms and amplifier circuitry as the predicate Otoport device and are designed to provide the same stimulations and register the same responses in the same conditions. This functional equivalence was verified by bench tests that compared the stimuli delivered and the response recorded by the 3 devices. OtoNova and OtoNova Pro are operated from a tablet controlling device running Nova-Link software. The Otoport is a self -contained test device with its own firmware.

For each device the electrical driving signals delivered by the device to the stimulator 'probe' transducers during testing were measured on subject and predicate devices using calibrated equipment for each testing mode (i.e. TEOAE DPOAE and ABR) and compared. They were found to be substantially the same (to within 1dB) across the functional frequency range.

The acoustic stimulation delivered by the probe into a standard calibrated acoustic ear simulator was recorded for subject and predicate devices for each test mode (TEOAE, DPOAE, ABR) and also for ABR test stimulation in the 'earcup' stimulus delivery device. They were found to be substantially the same (to within 1dB) across the functional frequency range.

The sensitivity of each device to simulated DPOAE, TEOAE and ABR responses was recorded by fitting the probe and electrodes to Otodynamics' factory-reference 'response simulator'. Each device received the same simulated response signals. The responses recorded by the OtoNova and OtoNova Pro were substantially the same levels (within 1dB) across the functional frequency for OAEs, and the ABR recorded had substantially the same size and waveform for ABR (within 1dB).

Summary of Clinical testing

The operational equivalence of OtoNova, OtoNova Pro and predicate Otoport OAE+ABR devices was verified from data collected from 20 volunteer adult subjects with informed consent , under identical clinical test conditions. The purpose of the trial to the compare physiological response measurement capacity and algorithms of the OtoNova and Otoport devices. Each subject was tested on each device with DPOAE, TEOAE or AABR, in the same session, with the same probe fitting (and electrode fitting for AABR), under the same test conditions. For each test mode data was recorded from a minimum 15 subjects from each device in the same session.

a. OtoNova's Nova-Link gives same screening test result under the same screening criteria (i.e. clear response, no clear response, invalid result) as the predicate device. The physical characteristics of the recorded responses were similar on each device. In the case of marginal response levels, where variability is to be expected, the range of marginality was no wider than for the Otoport OAE+ABR.
b. In the recording of OAE response for clinical purposes the OtoNova and OtoNova Pro the reported response levels were the same across frequency as with the Otoport OAE +ABR device within the tolerance expected due to subject movement.
c. The reported noise levels reported by Novalink were similar to those reported by the Otoport within the expected intrinsic variability of noise.

Based on the close agreement of the clinical test results obtained, and the equivalence of all the physical measurement characteristics of the devices as demonstrated in bench tests, on which the intended infant screening use solely depends, it is concluded that OtoNova and OtoNova Pro devices have the same efficacy

as the predicate device across all applications, including for infant screening.

Human Factors/ Usability Engineering Testing

The Human Factor (HF) engineering process applied to the OtoNova devices has been in accordance with ANSI/AAMI HE75:2009 Human factors Engineering – Design of medical devices and FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued February 3, 2016 and IEC 62366-1 Edition 1.0 2015-02.

A summative usability validation study was conducted with 16 participants external to Otodynamics. The study participants were asked to operate the device, run tests and provide user summative evaluation of the OtoNova medical device. The OtoNova simulated users, used only the OtoNova Quick Start guide- an essential OtoNova testing abbreviated IFU, the OtoNova IFU in case they needed further information, and the OtoNova device/ system items.

All the 16 users were able to sufficiently understand the OtoNova product/ IFU, to successfully record tests and use the medical device per its intended use, using only the instructions provided, the OtoNova product and items and the OtoNova User Manual. There were no substantial issues found during this OtoNova summative evaluation. The issues found were not substantial, and improvements were implemented.

User Manual

Improvements and changes to the OtoNova/Otonova Pro IFUs were made throughout the device's development and IFU change histories based on human factors testing data. Subsequently no substantial issues were found during further OtoNova/OtoNova Pro IFU summative evaluations or clinical applications.

Summative use evaluation for the user, patient and the environment concluded that the remaining residual risks are acceptable and that OtoNova as safe and effective as the predicate Otoport OAE+ABR device.

Biocompatibility Testing

The biocompatibility evaluation for the OtoNova Device was conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued September 4, 2023, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” FDA recognition number 258.

When used as intended, the OtoNova device will be placed in transient contact with the user’s skin during handling and Normal Use; the patient’s total cumulative exposure of the device is expected to be < 10 Minutes. The OtoNova device is therefore categorized according to ISO 10993-1 Fifth Edition 2020-08 as surface contacting devices that contact intact skin surfaces only.

Biological considerations for this categorization have included the following tests:

- Cytotoxicity,
- Sensitization, and
- Irritation or intracutaneous reactivity.

As such evaluation has been completed for compliance with the requirements of ISO 10993-5:2009-06-1 & ISO 10993-10:2010-08-01.

Cleaning Validation

The OtoNova Device cleaning processes identified in the product's Instructions for Use have been tested and validated and confirmed as appropriate when considering the intended purpose of the product.

This is to demonstrate that:

- The risks posed by contaminants and residues to the persons involved in the use of the device have been minimized.
- That the product has been designed and manufactured in such a way that it can be used safely with the materials and substances with which it will enter into contact during normal use; and,
- The manufacturing process is designed in such a way as to eliminate or reduce as far as possible the risk of infection to the User/patient.

A representative sample of the OtoNova device was acquired for testing along with production-equivalent label.

Electrical safety and electromagnetic compatibility (EMC)

Both electrical safety and EMC testing have been conducted on the OtoNova Device. The system complies with ANSI/AAMI/IEC ES60601-1:2005/(R)2012 and A1:2012 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 A1:2012 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 at all appropriate phases of the development process. Cybersecurity is addressed in the Software Risk Analysis and risk mitigation measures against cybersecurity risks are incorporated into the software requirements specifications.

CONCLUSIONS

The OtoNova Device has the same intended use as the predicate device.

Both the OtoNova and OtoNova Pro models are substantially equivalent to the Otoport/ Otocheck OAE+ABR predicate devices with respect to overall device functions and features.

Functional bench testing supported the electronic and acoustic equivalence of the subject and predicate devices, showing no significant impact on device function.

Clinical measurements supported the substantial equivalence of the audiological performance of the subject and predicate.

The primary technological differences are a result of the OtoNova device extending the use of Bluetooth technology, which already existing in the predicate device to achieve wireless control of the testing process, on a controlling processor with superior display capabilities.

Useability testing demonstrated that the ergonomic and dimensional differences do not negate the substantial equivalency of the subject device with the predicate on a clinical, biological and technological basis.

The non-clinical testing has supported the safety and functionality of the device.
The device is substantially equivalent to the predicate.