K122496

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510(k) SUMMARY

Manufacturer's Name:	Natus Medical Incorporated One Bio-logic Plaza Mundelein, IL 60060
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Telephone Number:	847.573.5430
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Summary Date:	October 23, 2012
Trade Name:	AuDX Pro Otoacoustic Emissions Measurement System
Common or Usual Name:	Audiometer
Classification Name and Number:	Audiometer 21 CFR 874.1050, Product Code: EWO
Predicate Devices:	K111618 AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function K112247 ABaer with ABaer I/O K072033 Otoport
Device Description:	The AuDX Pro Otoacoustic Emissions Measurement System is a handheld battery operated device that performs otoacoustic emissions tests. Connection to the patient's ear is via the Bio-logic ear probe. Using a combination of hardware and software, the system produces a controlled acoustic signal in the ear canal and measures the resulting evoked emissions that are generated by the outer hair cells of the inner ear associated with normal cochlear function. The stimuli are presented via miniature receivers and the acoustic response in the external ear canal is recorded via a miniature microphone, all embedded in the Bio-logic OAE probe. The system collects and averages data samples until specified measurement parameters are achieved. The AuDX Pro system includes optional software selections

distinguished by the AuDX Pro, AuDX Pro II, and AuDX Pro Plus naming designations.
The test consists of measuring and recording transient (click-evoked) otoacoustic emissions (TEOAE) or distortion product otoacoustic emissions (DPOAE) utilizing pure tones. The same ear probe is used for both types of tests. For transient otoacoustic emissions (TEOAEs), the reproducibility and the difference value between the TEOAE and the noise floor amplitudes appear on the LCD display on the front of the AuDX Pro unit. For distortion product otoacoustic emissions (DPOAEs), the DPOAE and noise floor amplitudes appear on the LCD. A pass or refer result is assigned at the end of the test based on a comparison of the patient's OAE response to normalized data. Additionally, a graphic display of the data is presented on the LCD allowing users to view and/or analyze the results.

The data collected by the AuDX system can be sent to a host computer where it can be saved or placed in a database. Optional Natus software programs are available for that function. Natus software programs provide a mechanism for users to define their own specific test protocols and download them to the AuDX Pro device.

The AuDX Pro Otoacoustic Emissions Measurement System expands upon the capabilities of the AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function [K111618]. The AuDX Pro System provides the following enhancements over the AuDX System:

- Protocol Setup utilities to load expanded frequency protocols to the AuDX Pro;
- Options to upload data to a PC based Patient and Test Information Database (P&TI);
- Options to graphically review data from a PC based Hearing Assessment & Tracking System (HATS) software utility linked with the P&TI Database; and,
- A Graphical User Interface (GUI) on an enhanced LCD screen for testing, patient information, and data review.

Intended Use:

The AuDX Pro Otoacoustic Emissions Measurement System is indicated for use when it is necessary for a trained health care professional to assess cochlear function. The device can be used for patients of all ages, from newborn infants through adults, to include geriatric patients. The otoacoustic emissions test is especially indicated for use in testing individuals for whom behavioral responses are deemed

	unreliable, such as infants, young children, and cognitively impaired adults.
Technological Characteristics:	The AuDX Pro Otoacoustic Emissions Measurement System performs transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE) tests. Using a combination of hardware and software, the AuDX system produces a controlled acoustic signal in the ear canal and measures the resulting evoked emissions that are generated by the inner ear as a result of normal cochlear function. The stimuli are presented via miniature receivers and the acoustic response in the external ear canal is recorded via a miniature microphone, all embedded in the Bio-logic OAE probe. The system collects and averages data samples until specified measurement parameters are achieved. For transient evoked otoacoustic emissions (TEOAEs), the reproducibility and the difference value between the TEOAE and the noise floor amplitudes are calculated and presented to the user. For distortion product otoacoustic emissions (DPOAEs), the DP and noise floor amplitudes are calculated and presented to the user. A pass or refer recommendation is assigned automatically at the end of the test based on user defined custom protocols or default test protocols and measured OAE test parameters. The AuDX Pro Otoacoustic Emissions Measurement System is equivalent to the devices cleared under K111618, K112247, and K072033.
Nonclinical Tests:	Design verification and validation were performed to assure that the AuDX Pro meets its performance specifications and demonstrates equivalence to the specified predicate devices. The verification and validation summary report and risk analysis documentation provided in this 510(k) support the conclusion that the AuDX Pro Otoacoustic Emissions Measurement System is safe and effective.

Comparison Table

	AuDX with AuDX I/O Function	ABaer with ABaer I/O Function	Otodynamics Otoport	AuDX Pro
Predicate 510(k) number	**K111618**	**K112247**	**K072033**	**New device**
Intended Use	To measure or determine cochlear function via performing transient evoked otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE) and determining DPOAE Input / Output (I/O) functions.	Performs an automated auditory evoked response (ABaer) screening and/or an automated otoacoustic emissions (AOAE) screening. The device performs TEOAE and DPOAE tests and determining DPOAE Input / Output (I/O) functions.	Can perform automated TEOAE and DPOAE based measurements via an ear probe, including I/O functionality.	To measure or determine cochlear function via performing transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE).
User	Trained health care professionals	Same	Same	Same
Patient Population	Newborn infants through adults, to and including geriatric patients. Especially for use in testing individuals where behavioral audiometric results are unreliable.	Same	Same	Same
Anatomical sites	External ear canal	External ear canal for OAE and for ABR testing; scalp, ear and other skin sites proper for surface electrode placement.	External ear canal	External ear canal
Noninvasive	Yes	Yes	Yes	Yes
Physical Form	Standalone handheld system that can be connected to a PC.	PC based system with handheld size external data acquisition box.	Standalone handheld system.	Standalone handheld system that can be connected to a PC.
DPOAE	Yes	Yes	Yes	Yes
I/O function	Yes	Yes	Yes – Otoport Advance	No
TEOAE	Yes	Yes	Yes	Yes
ABR	No	Yes	No	No
Can provide Pass/Refer recommendation	Yes	Yes	Yes	Yes
Background noise check during test	Yes	Yes	Yes	Yes
Measurement based stopping criteria	Yes	Yes	Yes	Yes
Performs in-the-ear calibration	Yes	Yes	Yes	Yes
User customization of test protocols	Yes – User has control over DPOAE I/O function test parameters, but not automated DPOAE or TEOAE testing.	Yes – User has control over DPOAE I/O function test parameters, but not automated DPOAE or TEOAE testing.	Yes, Can create, edit and save user's own test protocols and pass/refer criteria for automated DPOAE, TEOAE and DPOAE I/O testing.	Yes, Can create, edit and save user's own test protocols and pass/refer criteria for automated DPOAE and TEOAE testing.

	AuDX with AuDX I/O Function	ABaer with ABaer I/O Function	Otodynamics Otoport	AuDX Pro
Predicate 510(k) number	**K111618**	**K112247**	**K072033**	**New device**
Fundamental Scientific Technology	Records data in the form of acoustic signals, i.e. OAE with the use of an ear probe. The probe houses miniature receivers to deliver a stimulus and a microphone to records stimulus and the resulting evoked OAEs. The test consists of either measuring and recording TEOAEs or DPOAEs. Sensed signals are amplified, filtered and averaged to improve the signal quality and signal-to-noise ratio. The resulting recorded measurements are automatically displayed and can be evaluated for OAE signals. I/O software feature to the DPOAE test suite provides ability to allow the user to change the stimulus levels at constant stimuli frequencies and plot the corresponding stimulus amplitude vs DPOAE level functions to evaluate the input/output relations of the generated DPOAEs at specific frequency regions as defined by the user.	Same as K111618 with respect to OAE testing (TEOAE, DPOAE and DPOAE I/O). Additionally, the device performs screening by recording and analyzing Auditory Brainstem Responses (ABR).	Can screen for cochlear function using either Transient Evoked or Distortion Product Otoacoustic Emissions (TE or DPOAEs). It uses an ear probe to deliver stimulus and to record evoked OAEs. Recorded signals are evaluated automatically using signal analysis to provide robust indications of cochlear function and high immunity to extraneous noise. Additionally, the system includes I/O functionality.	Same as K111618, K112247 and K072033 with respect to TEOAE and DPOAE.
Safety Characteristics	No direct electrical connection to the patient.	Same	Same	Same
Energy delivered to the patient	Audible acoustic stimulus to the subject's auditory system.	Same	Same	Same
Energy delivered to the patient	Audible acoustic stimulus to the subject's auditory system.	Same	Same	Same
Energy delivered to the patient	Audible acoustic stimulus to the subject's auditory system.	Same	Same	Same

	AuDX with AuDX I/O Function	ABaer with ABaer I/O Function	Otodynamics Otoport	AuDX Pro
Predicate 510(k) number	**K111618**	**K112247**	**K072033**	**New device**
Energy delivered to the patient	Audible acoustic stimulus to the subject's auditory system.	Same	Same	Same
Mechanical safety	No moving mechanical parts in contact with the subject	Same	Same	Same
Electrical Safety and Performance Standards	CISPR 11, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 610003-2, IEC 610003-3, IEC 610004-2, IEC 610004-3, IEC 610004-4, IEC 610004-5, IEC 610004-6, IEC 610004-8, IEC 610004-11, IEC 60101-1-4	CISPR 11, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 610003-2, IEC 610003-3, IEC 610004-2, IEC 610004-3, IEC 610004-4, IEC 610004-5, IEC 610004-6, IEC 610004-8, IEC 610004-11, IEC 60101-1-4	BS EN 60601-1, BS EN 60601-1-1, BS EN 60601-1-2, BS EN 60601-1-4	CISPR 11, IEC 60601-1 + Coor. 1 + Coor. 2, IEC 60601-1-2 + A1, IEC 610003-2, IEC 610003-3 + A1 + A2 IEC 610004-2, IEC 610004-3, IEC 610004-4, IEC 610004-5, IEC 610004-6, IEC 610004-8, IEC 610004-11, IEC 60101-1-4
Battery powered hardware (Battery type)	Yes (Rechargeable Lithium Ion Battery)	No (6 V DC)	Yes (Rechargeable Lithium polymer)	Same as K111618
Data display	Information displayed on the AuDX screen and the PC monitor screen for the AuDX I/O	Information displayed on computer monitor screen.	Information displayed on the Otoport device screen.	Information displayed on the device's LCD screen and can be displayed on a computer monitor screen.
Built in keys for user interface on the collection box	Yes, 5-keys	No	Yes	Yes, 7-keys
Computer compatibility	IBM compatible PC.	Same	Same	Same
Operating System	Windows for host PC for AuDX I/O and utilities. No OS for the AuDX hardware device.	Windows® 2000, Windows® XP, Windows® 7	Windows 2000/XP/Vista for PC based utilities	No OS for the AuDX hardware device.
Communication with PC	RS-232 and USB	RS-232 and USB	USB	RS-232 and USB
System Design	With respect to TEOAE and DPOAE, the main stimulus generation and data acquisition hardware connected to OAE probe. For the AuDX I/O functionality, the main stimulus generation and data acquisition hardware connected to OAE probe and a personal computer hosting testing software, data display and user interface.	Main stimulus generation and data acquisition hardware connected to patient cables, transducers and personal computer hosting testing software, data display and user interface.	Main stimulus generation and data acquisition hardware connected to OAE probe and hosting the testing software, data display and user interface functionality without a need to connect to PC.	Main stimulus generation and data acquisition hardware connected to OAE probe.

	AuDX with AuDX I/O Function	ABaer with ABaer I/O Function		AuDX Pro
Predicate 510(k) number	**K111618**	**K112247**		**New device**
Uses disposable ear tips (silicon and foam ear tips)	Yes	Yes	Yes	Yes
Biocompatibility	Ear tip materials are classified by ISO 10993-1 as surface-contacting devices / limited exposure to skin. Tests: Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), and Irritation (ISO 10993-10)	Same	Info not available	Same
Sterility	None required	Same	Same	Same
Built-in LCD Screen	Yes	Yes	Yes	Yes
Transducers	Bio-logic OAE Ear Probe	Bio-logic OAE Ear Probe for OAE tests. TDH-39 earphones, insert earphones, bone conductor oscillator for ABR tests.	Otodynamics OAE ear probe	Bio-logic OAE Ear Probe
Software and Firmware	The handheld AuDX hardware runs the firmware written in assembly code that controls the stimulus generation, data collection and analysis for OAE testing. The AuDX I/O software feature is written in C++ language and mainly provides the convenient PC-based user interface and communicates with the data collection hardware.	Firmware is written entirely in ADSP-219x assembly language. This allows for direct and efficient control of the DSP and associated hardware. Software is written in Microsoft Visual Studio C++.	Firmware controls the stimulus presentation, data collection and evaluation. Specific development language is not available from competitive product information.	The handheld AuDX Pro hardware runs the firmware written in assembly code that controls the stimulus generation, data collection and analysis for OAE testing.
Reports	Data files can be printed	A single patient report can be printed based on a default template. Four types of multi-patient reports are available (basic, extended, complete and custom). Additionally, statistical reports can be generated.	A single patient report can be printed via Otolink accessory software. There are two print formats: one to print the results of a single ear and the other prints the results of two tests, one for each ear.	Similarly, a single patient report can be printed. There are two print formats: one to print the results of a single ear and the other prints the results of two tests, one for each ear.
Patient & Test Information Database (P&TI)	No	Yes, includes predefined fields, customizable layout, edit feature, search feature, sort feature, form & table views, archival / copy feature, backup feature, repair feature, compact feature and import tool.	Similarly, data can be transferred to PC via Otolink accessory software.	Similarly, AuDX Pro is able to store data in and configure common P&TI database like ABaer.

	AuDX with AuDX I/O Function	ABaer with ABaer I/O Function	Otodynamics Otoport	AuDX Pro
Predicate 510(k) number	**K111618**	**K112247**	**K072033**	**New device**
Hearing Assessment & Tracking System (HATS)	No	Yes. The HATS utility enables AuDX Pro data to be exported to HiTrack via ABaer.	Similarly, Otolink accessory software enables transfer of data to HiTrack.	Yes. The HATS utility extracts data from the AuDX Pro box and enables the exportation to HiTrack via ABaer.
Microphone frequency response	100 Hz - 10 kHz ± 3 dB	Same	Info not available	Same
Microphone sensitivity (@1 kHz re 1V/Pa)	-33 dB	Same	Info not available	Same
Speaker frequency bandwidth	100 Hz – 10 kHz ± 5 dB	100 Hz – 10 kHz ± 5 dB	500Hz – 6000Hz	100 Hz – 10 kHz ± 5 dB
System Signal-to-noise ratio	~85 dB	Same	Same	Same
Speaker sensitivity	90 dB SPL (@ 1kHz re 1 VAC Drive)	92 dB re 1 VAC	Info not available	90 dB SPL (@ 1 kHz re 1 VAC Drive)
Maximum stimulus output	<95 dB	Same	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 1 2012

Natus Medical Incorporated
c/o Mr. Timothy Karlovsky
Quality and Regulatory Assurance Manager
One Bio-logic Plaza
Mundelein, IL 60060

Re: K122496
Trade/Device Name: AuDX Pro Otoacoustic Emissions Measurement System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: August 15, 2012
Received: August 16, 2012

Dear Mr. Karlovsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122496

Device Name: AuDX Pro Otoacoustic Emissions Measurement System

Indications for Use:

The AuDX Pro Otoacoustic Emissions Measurement System delivers controlled acoustic signals in the ear canal and measures the resulting evoked otoacoustic emissions (OAEs) that are generated by the outer hair cells of the inner ear. The AuDX Pro device performs transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE) tests.

AuDX Pro is indicated for use by trained health care professionals (audiologists, physicians) and personnel (nurses, technicians) who are trained to operate the device under their supervision to perform otoacoustic emissions testing to assess cochlear function.

The device can be used for patients of all ages, from newborn infants through adults, to include geriatric patients. The otoacoustic emissions test is especially indicated for use in testing individuals for whom behavioral results are deemed unreliable, such as infants, young children, and cognitively impaired adults.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K122496