K111618

DEC 2 8 2011

natus®

510(k) SUMMARY

Manufacturer's Name:	Natus Medical Incorporated One Bio-logic Plaza Mundelein, IL 60060
Corresponding Official:	Martha M. Kadas Director Quality Assurance and Regulatory Affairs Natus Medical Incorporated One Bio-logic Plaza Mundelein, IL 60060
Telephone Number:	847.573.5409
Fax Number:	847.949.8615
Summary Date:	May 31, 2011
Trade Name:	AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function
Common or Usual Name:	Audiometer
Classification Name and Number:	Audiometer 21 CFR 874.1050, Product Code: EWO
Predicate Devices:	K021801 ABaer Cub with Automated OAE and ABR K964132 Bio-logic Scout and Scout Sport Otoacoustic Emissions (OAE) Test Instruments with TEOAE and DPOAE Software, incorporating the modifications of Automated Input / Output Software Functions K974076 Sport / AuDX OAE Test Instrument with Bio-logic Ear Probe K072033 Otodynamics Otoport
Device Description:	The AuDX I/O Function is a Windows® based software application for use with the AuDX Otoacoustic Emissions Measurement System. The AuDX I/O software enables the AuDX device user to perform DPOAE testing at different test frequencies, frequency ratios and intensity levels. The graphical representation of the test results in the form of stimulus level presented versus measured DPOAE level provides an effective way for the user to view and evaluate

	stimulus level-sensitive information about DPOAE responses.
Intended Use:	The 'AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function" is indicated for use when it is necessary for a trained health care professional to measure or determine 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.
Technological Characteristics:	The AuDX 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 hearing process. The stimuli are presented via miniature receivers and the sounds in the external ear canal are 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 at the end of the test automatically based on user defined custom protocols or default test protocols and measured OAE test parameters. With respect to TEOAE and DPOAE testing, the AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function is equivalent to the devices cleared under K021801, K964132, K974076, and K072033. The AuDX I/O is a software option to be used in conjunction with the AuDX system. The standard DPOAE test measures otoacoustic response to a series of frequency-pairs of tones, varying the frequency while keeping the level or intensity of the stimulus tones at a constant level. The AuDX I/O

software option enables the AuDX device user to perform DPOAE testing at different stimulus intensities in order to obtain the 'DPOAE Input / Output (I/O) function' for user defined test frequencies, frequency ratios and intensity levels. The graphical representation of the test results in the form of stimulus level vs. DPOAE level provides an effective way for the user to view and evaluate stimulus level-sensitive information about DPOAE response.

With respect to DPOAE I/O function, the AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function is equivalent to the automated Input / Output Software functions present in the Scout and Scout Sport Otoacoustic Emissions (OAE) Test Instruments.

Nonclinical Tests:

Design verification and validation were performed to assure that the AuDX I/O Function meets its performance specifications and demonstrates equivalence to the Automated I/O function present in the Scout and Scout Sport OAE Test Instruments.

The verification and validation summary report and risk analysis documentation provided in this 510(k) support the conclusion that the AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Natus Medical Incorporated
c/o Martha M. Kadas
Director Quality Assurance and Regulatory Affairs
One Bio-logic Plaza
Mundelein, IL 60060

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Re: K111618
Trade/Device Name: AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: December 1, 2011
Received: December 2, 2011

Dear Ms. Kadas:

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

K111618

Indications for Use

510(k) Number (if known): K111618

Device Name: AuDX Otoacoustic Emissions Measurement System with AuDX I/O Function

Indications for Use:

The AuDX Otoacoustic Emissions Measurement System produces 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 as a result of normal peripheral hearing processes. The AuDX device performs both transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE) tests that can be utilized in hearing screening and diagnostic test environments. The AuDX I/O is a software option intended to provide additional diagnostic capability and to be used in conjunction with the AuDX system. The AuDX I/O software option enables the AuDX device user to perform DPOAE testing at different stimulus intensities in order to obtain the 'DPOAE Input / Output (I/O) function' at different test frequencies, frequency ratios and intensity levels. The graphical representation of the test results in the form of stimulus level presented versus measured DPOAE level at each tested frequency provides an effective way for the user to view and evaluate stimulus level-sensitive information about DPOAE responses.

As an OAE based screening tool, AuDX is indicated for use by any personnel (nurses, technicians, volunteers) who are trained to operate the device for the purpose of performing an objective, automated physiologic screening measure with pass/refer result requiring no further clinical interpretation. Additionally, as a tool that can provide diagnostic information, the device is indicated for use by trained health care professionals (audiologists, physicians) to further assess cochlear function for the purpose of diagnosis and treatment of hearing disorders, since additional information may be obtained by viewing the details of the performed otoacoustic emissions test and by obtaining the DPOAE I/O functions.

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.

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

510(k) Number K111618

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)

Prescription Use X
(Per 21 CFR 801.109)