K112247

APR - 2 2012

510(k) SUMMARY

Manufacturer's Name:	Natus Medical Incorporated One Bio-logic Plaza Mundelein, IL 60060
Corresponding Official:	Don Williams Vice President and General Manager Natus Medical Incorporated One Bio-logic Plaza Mundelein, IL 60060
Telephone Number:	800.323.8326 ext. 5424
Fax Number:	847.949.8615
Summary Date:	March 28, 2012
Trade Name:	ABaer with ABaer I/O Function
Common or Usual Name:	Audiometer and Evoked response auditory stimulator
Classification Name and Number:	Audiometer 21 CFR 874.1050, Product Code: EWO Evoked response auditory stimulator 21 CFR 882.1900 Product Code: GWJ
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 K072033 Otodynamics Otoport
Device Description:	The ABaer I/O Function is a Windows® based software application for use with the ABaer Hearing Screening System. The ABaer I/O software option enables the ABaer device user to perform DPOAE Input/Output (I/O) testing at different test frequencies, frequency ratios and intensity levels in addition to the ABR and OAE based hearing screening functions. 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 'ABaer System with ABaer 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 ABaer Hearing Screening System (HSS) performs an automated auditory evoked response (ABaer) screening and/or an automated otoacoustic emissions (AOAE) screening. The automated auditory brainstem response test (ABaer) involves placement of three recording electrodes on an infant's head. The electrodes record electrical activity generated by the auditory nervous system that results from the presentation of a click stimulus into the patient's ear via acoustic transducers (i.e. insert earphones, headphones, OAE probe, acoustic ear couplers). The system collects and averages evoked potential data in order to perform ABR based screening, recording and analysis functions, provides one channel of data recording, and includes the Point Optimized Variance Ratio (POVR) algorithm for optimizing signal quality, implementing the automated screening function and enhancing speed of test completion in the same manner as in the predicate device (K021801). The device presents the resulting POVR score and a Pass/Refer recommendation to the user. With respect to the ABR based testing, the ABaer with ABaer I/O Function is equivalent to the predicate device cleared under K021801. The automated otoacoustic emissions (AOAE) screening functionality of the ABaer system involves producing controlled acoustic signals in the ear canal and measures the resulting evoked otoacoustic emissions that are generated by the inner ear as a result of normal hearing processes. The ABaer device performs both distortion product otoacoustic emissions (DPOAE) tests and transient evoked otoacoustic emissions (TEOAE) tests.

The OAE stimuli are generated 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, averages and analyzes data samples until specified measurement and test 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 the test protocol parameters and measured OAE parameters.

With respect to TEOAE and DPOAE testing, the ABaer with ABaer I/O Function is equivalent to the devices cleared under K021801, K964132, and K072033.

The ABaer I/O is a software option to be used in conjunction with the ABaer 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 ABaer I/O software option enables the ABaer 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 ABaer with ABaer 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 ABaer with ABaer I/O Function meets its performance specifications and demonstrates equivalence to the functionalities present in the respective predicate devices.

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

Components:

Hardware	
580-ABAER2	ABaer Data Collection Box
580-SINABR-008	Insert Earphones
206920	Halo Adaptors & tubes
580-MEPTDH-125	Headphones
301663	Alligator Clips (3)
580-PROAE3	OAE Style Probe
541-ABRC10-008	Patient Cable – 3 inputs
541-USB001	USB Cable (ABaer & Printer)
520-PSVDC	Power Supply for ABaer module
540-LINECD-012	Power Cord – 12 inch
001308	Seiko Smart Label Printer
541-SEKBLE	Printer Serial Cable
520-SEK120	Printer Power Supply
520-AMPS01	Isolation Transformer – 3 outlet (laptop only)
520-SWBXFS	Isolation Transformer – 6 outlet (touchscreen only)
541-CORD12	Power Cord for Isolation Transformer
541-TSTCBL	Loop Test Cable
001771	Panel PC
001316	Notebook PC
Software	
008634	ABaer Software
008164	ABaer I/O Function Software

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 Inc.
c/o Mr. Don Williams
Vice President and General Manager
One Bio-Logic Plaza
Mundelein, IL 60060

APR - 2 2012

Re: K112247
Trade/Device Name: ABaer with ABaer I/O Function
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: February 28, 2012
Received: February 29, 2012

Dear Mr. Williams:

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

K112247

Indications for Use

510(k) Number (if known): K112247

Device Name: ABaer with ABaer I/O Function

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The Hearing Screening System (HSS) ABaer performs an automated brainstem auditory evoked response (ABaer) screening and/or an automated otoacoustic emissions (AOAE) screening. The automated auditory brainstem response test (AABR) involves placement of three recording electrodes on an infant's head. The electrodes record the electrical activity generated by the auditory nervous system that result from presentation of a click stimulus into the ear. The automated otoacoustic emissions (AOAE) screening involves producing controlled acoustic signals in the ear canal and measuring the resulting evoked otoacoustic emissions that are generated by the inner ear as a result of normal hearing processes. The ABaer device performs both distortion product otoacoustic emissions (DPOAE) tests and transient evoked otoacoustic emissions (TEOAE) tests.

The ABaer I/O is a software option to be used in conjunction with the ABaer 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 ABaer I/O software option enables the ABaer 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 presented versus measured DPOAE level provides an effective way for the user to view and evaluate stimulus level-sensitive information about DPOAE responses. DPOAE threshold is the lowest stimulus intensity level which produces DPOAE response amplitude that is distinguishable from the level of system distortion and from the noise floor. DPOAE threshold is expressed in much of the published literature as the lowest intensity of the F2 stimulus that generates a clear DPOAE response. DPOAE threshold does not equate to and should not be confused with audiometric and auditory threshold. Whereas auditory threshold measures assess the integrity of the entire auditory system from outer ear to cortex, DPOAE threshold measures, which the user can interpret from the DPOAE I/O functions, are limited to assessment of outer hair cell function in the cochlea only.

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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)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112247

Prescription Use X
(Per 21 CFR 801.109)