K121512

JUL 26 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:	May 18, 2012
Trade Name:	Scout Sport Otoacoustic Emissions Measurement System
Common or Usual Name:	Audiometer
Classification Name and Number:	Audiometer 21 CFR 874.1050, Product Code: EWO
Predicate Devices:	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 K112247 ABaer with ABaer I/O Function
Device Description:	The Scout Sport 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 Scout Sport device performs transient evoked otoacoustic emissions (TEOAE), distortion product otoacoustic emissions (DPOAE), and DPOAE Input/Output (I/O) tests.
Intended Use:	Scout Sport 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 TEOAE, DPOAE, and DPOAE I/O functions to assess cochlear function.

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The device can be used for patients of all ages, from 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 Scout Sport 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 Scout Sport 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 predefined test protocols and measured OAE test parameters.

DPOAE I/O is a software option. 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 DPOAE I/O software option enables the Scout Sport 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.

The functionality of the Scout Sport system has been enhanced by addition of the following Scout software program modules: the Patient and Test Information database

(P&TI), the BLReports application, and additional peripheral software utilities.

The Patient and Test Information database (P&TI) is used to store, display, and manage patient and test information records. The database stores the following:

- Patient demographic information such as Patient Name, Patient ID, Doctor Information, and comments; and,
- Test demographic information such as ID, Test Dates, and Test Results

The standalone BLReports application provides customizable reporting for Scout. The Scout application must invoke BLReports directly, passing the data necessary to create and use report templates. The report templates are made up of template components that can be added, modified or removed by the user.

The additional peripheral software utilities consist of the Feedback utility and the database Repair utility. The Feedback utility enables users to create an archive containing recent logs, databases, registry data and system information to be copied on a CD and provide to Natus Technical Support to assist in troubleshooting. The database Repair utility enables the repair and compaction of databases.

Nonclinical Tests:

Design verification and validation were performed to assure that the Scout Sport Otoacoustic Emissions Measurement System 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 Scout Sport Otoacoustic Emissions Measurement System 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

JUL 26 2012

Natus Medical Incorporated
c/o Don Williams
Vice President and General Manager
One Bio-logic Plaza
Mundelein, IL 60060

Re: K121512
Trade/Device Name: Scout® Sport Otoacoustic Emissions Measurement System
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO
Dated: May 18, 2012
Received: May 21, 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

K121512

Indications for Use

510(k) Number (if known): K121512

Device Name: Scout Sport Otoacoustic Emissions Measurement System

Indications for Use:

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Scout Sport 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.

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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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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