DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 22, 2014

Natus Medical Incorporated
Ms. Judy Buckham
Regulatory Affairs Associate
5900 First Avenue South
Seattle, WA 98108

Re: K141446
Trade/Device Name: Echo-Screen III Pro
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ, EWO
Dated: July 23, 2014
Received: July 24, 2014

Dear Ms. Buckham,

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Eric A. Mann -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141446

Device Name
Echo-Screen III

Indications for Use *(Describe)*
The Echo-Screen III hearing screener models are based upon otoacoustic emission (OAE) and auditory brainstem response (ABR) technology.

The device is intended to screen hearing for newborns through adults, including geriatric patients. The device does not measure hearing per se, but helps to determine whether or not a hearing loss may be present.

The Echo-Screen III product family consists of handheld, automated OAE and ABR based hearing screening systems which are easy to use. The measurement flow is menu guided and the evaluation is based upon signal statistics. The Echo-Screen III devices are intended to be used by trained personnel in a medical or school environment. The Echo-Screen III models are not intended for fitting assistive listening devices such as hearing aids or cochlear implants.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

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510(k) SUMMARY
Echo-Screen III

Manufacturer's Name: Natus Medical Incorporated
5900 First Avenue South
Seattle, WA 98108

Corresponding Official: Judy Buckham
Regulatory Affairs Associate

Telephone Number: 206 268 5187
Fax Number: 206 268 5104

Summary Date: August 21, 2014

Trade Name: Echo-Screen III

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 Device: K013977 Echo-Screen T, TA, TD, TDA, TC

Device Description:

The Echo-Screen III hearing screener is a portable, handheld, battery-operated device that can detect hearing loss using Otoacoustic Emission or Auditory Brainstem Response screening technologies. The Echo-Screen III may be configured to support one or any combination of TEOAE, DPOAE, and AABR technologies.

The device represents the next generation of the Echo-Screen product line with key enhancements over the previously cleared predicate Echo- Screen T, TA, TD, TDA, TC [K013977], hereinafter referred to as the Echo-Screen T series; specifically, use of the Android operating system, programming upgrade to C and Java languages, addition of a color screen and built-in full hardware keyboard plus icons and on-screen touch keyboard, optional barcode scanner, Li-ion rechargeable battery, and inclusion of a docking station for battery charging and data transfer.

Intended Use:

The Echo-Screen III hearing screener models are based upon otoacoustic emission (OAE) and auditory brainstem response (ABR) technology.

The device is intended to screen hearing for newborns through adults, including geriatric patients. The device does not measure hearing per se, but helps to determine whether or not a hearing loss may be present.

The Echo-Screen III product family consists of handheld, automated OAE and ABR based hearing screening systems which are easy to use. The measurement flow is menu guided and the evaluation is based upon signal statistics. The Echo-Screen III devices are intended to be used by trained personnel in a medical or school environment. The Echo-Screen III models are not intended for fitting assistive listening devices such as hearing aids or cochlear implants.

Technological Characteristics:

Both the Echo-Screen III and the predicate Echo-Screen T series perform transient evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE) tests. The devices produce a controlled acoustic signal in the ear canal and measure 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 OAE probe. For TEOAE, the stimulus consists of short duration, transient nonlinear acoustic click trains. For DPOAE, the stimulus consists of pure tone pairs.

- For TEOAEs, the system uses a binomial statistical test to give either a Pass or Refer result. The device calculates the statistical probability that an emission has been recorded at a succession of sampling points ranging from 6 to 12 ms after the stimulus.
- For DPOAEs, the system applies a statistical algorithm to discriminate the sound of the environment (noise) from the cochlear sound response. Based upon criterion set up for four f_2 frequencies, a Pass or Refer result is determined.

Automated auditory brainstem response (AABR®) testing involves the placement of three recording electrodes on the patient's head. The electrodes record electrical activity generated by the auditory nervous system that result from the presentation of a stimulus into the ear. The stimulus for ABR is a short duration, transient broadband acoustic stimulus, i.e., acoustic click / ultra-short frequency sweeps or chirps. The AABR technology uses a statistical approach for the Pass criteria that is based on binomial statistics.

The TEOAE, DPOAE, and ABR screening test performance of the Echo-Screen III is equivalent to the performance of the predicate Echo-Screen T series.

Clinical Tests: N/A

Nonclinical Tests:

Design verification and validation were performed to assure that the Echo-Screen III meets its performance specifications and demonstrates equivalence to the specified predicate device.

Conclusions:

The verification and validation summary and risk analysis documentation provided in this 510(k) support the conclusion that the Echo-Screen III is safe and effective.

The Echo-Screen III is substantially equivalent to the Echo-Screen T series cleared under K013977.