OCT 1 6 2001

natus®

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013137

A. Submitter:

Natus Medical, Inc.
1501 Industrial Road
San Carlos, CA 94070

phone: (650) 802-0400
fax: (650) 802-6621

Contact: Sheila Ramerman

Date Prepared: October 12, 2001

B. Device Names:

Classification name	Stimulator, Auditory Evoked Response
Common/usual name	Hearing Screener
Proprietary name	ALGO® 3 Newborn Hearing Screener

C. Predicate Device: ALGO-2 Newborn Hearing Screener, K936039

D. Device Description:

Like the predicate device, the ALGO 3 detects the auditory brainstem response (ABR) to a series of stimulus clicks ('clicks'), which screens the entire hearing pathway from the outer ear to the brainstem. The ABR is not affected by the status of the middle ear, and evaluation of middle ear status is not required prior to ABR detection. The ALGO 3 generates soft clicks at 35 dB nHL ('normal hearing level' scale) which are delivered to the infant's ears through an Acoustic Transducer Assembly cable (ATA) to disposable earphones (Flexicouplers™ Disposable Earphones); a 35 dB nHL stimulus will detect a 30 dB nHL hearing loss. Each click evokes a series of identifiable brain waves from the auditory brainstem area of the infant's brain. Sensors (Jelly Tab™ Sensors) applied to the infant's skin pick up the brain wave response and transmit the signals to the screener via the Patient Cable Attachment (PCA) and Preamplifier (Preamp) assemblies. The screener uses advanced signal processing technology to separate the ABR from background noise and from other

brain activity. The ALGO 3 automatically compares the baby's ABR to a template of ABRs derived from normal hearing infants (automated auditory brainstem response technology, AABR), and prints a "PASS" or "REFER" result. A "PASS" result is printed if the ALGO 3 can establish, with > 99% statistical confidence, that an ABR is present and consistent with its template. A "REFER" result is printed if the ALGO 3 cannot detect an ABR response with sufficient statistical confidence or one that is consistent with the template. A built-in printer automatically prints results on a self-adhesive label, which can be affixed directly to the infant's medical chart.

The ALGO 3 is also capable of screening using clicks at 40 dB nHL. Some newborn hearing programs prefer to screen at 40 dB nHL (international programs, for example), and some domestic legislative requirements set the screening threshold at 40 dB nHL rather than at 35. The incorporation of a 40 dB screening application in the ALGO 3 device makes the device more useful to more users.

The ALGO 3 device is easy enough for trained volunteers and other trained non-medical personnel to use. Interpretation of screening results is not required, as the screener automatically determines if the response is consist with a template and automatically generates a "PASS" or "REFER" result, as previously discussed. In addition, training is minimal because of the easy-to-navigate graphical user interface, HELP topics in software, and a user tutorial in the ALGO 3 software.

Screening results can be tracked using the integrated ALGO DataBook® NHS Data Tracking System software. The DataBook utility retrieves and displays patient and screening data stored in ALGO 3 software. Data can be viewed on the ALGO 3's display; can be saved as an ASCII file on diskette for data management and reporting purposes; and can be exported to other databases for data management and reporting purposes.

There are no user-adjustable parameters, so that each screen is performed under exactly the same conditions. Click rate, click intensity, impedance threshold, and noise rejection thresholds are all pre-programmed into the device software, and users cannot change these screening parameters.

The ALGO 3 is composed of the following components, as is the Predicate Device:

- Screening module, with laptop computer
- Printer module, with label printer
- Cable assemblies (ATA, PCA, Preamp)
- Cart for transport and component storage
- Screening and accessory supplies

Accessories available for use with the ALGO 3 include single-use, disposable FlexiCouplers Disposable Earphones, and single-use, disposable Jelly Tab Sensors.

E. Intended Use:

The ALGO® 3 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR® technology. The screener is intended for babies between the ages of 34 weeks (gestational age) and 6 months. Babies

should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening.

The screener is simple to operate. It does not require special technical skills or interpretation of results. Basic training with the equipment is sufficient to learn how to screen infants who are in good health and about to be discharged from the hospital. A typical screening process can be completed in 15 minutes or less. Sites appropriate for screening include the well-baby nursery, NICU, mother's bedside, audiology suite, outpatient clinic, or doctor's office.

F. Comparison with the Predicate Device:

The ALGO 3 Newborn Hearing Screener is a hardware, software, supplies, and materials modification of the ALGO-2 Newborn Hearing Screener (K936039). The ALGO 3 and the ALGO-2 Newborn Hearing Screeners have the same intended use and use the same operating principle.

Based on the data and information presented here, the modified ALGO 3 Newborn Hearing Screener and Accessories are substantially equivalent to the ALGO-2 Newborn Hearing Screener and Accessories manufactured and distributed by Natus Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

Ms. Sheila Ramerman
Director, Regulatory Affairs
Natus Medical, Inc.
1501 Industrial Road
San Carlos, California 94070-4111

Re: K013137
Trade Name: ALGO® 3 Newborn Hearing Screener
Regulation Number: 882.1900
Regulation Name: Evoked Response Auditory Stimulator
Regulatory Class: Class II
Product Code: GWJ
Dated: September 18, 2001
Received: September 19, 2001

Dear Ms. Ramerman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MP

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013137

Device Name: ALGO® 3 Newborn Hearing Screener and Accessories

Indications for Use:

The ALGO® 3 Newborn Hearing Screener is a mobile, noninvasive instrument used to screen infants for hearing loss. The screener uses AABR® technology. The screener is intended for babies between the ages of 34 weeks (gestational age) and 6 months. Babies should be well enough to be ready for discharge from the hospital, and should be asleep or in a quiet state at the time of screening.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013137