K030823

510(k) Summary

APR 0 9 2003

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

Contact: Ronald Kohlhardt

Date Summary Prepared: March 9, 2003

Device Trade Name:

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

Predicate Device: ALGO 3 Newborn Hearing Screener, K013137

Intended Use:

The ALGO® 3*i* Newborn Hearing Screener is a portable, noninvasive instrument used to screen infants for hearing loss. The screener uses Natus 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.

Comparison with the Predicate Device:

The ALGO 3*i* Newborn Hearing Screener is a modification of the ALGO 3 Newborn Hearing Screener. The ALGO 3*i* and the ALGO 3 Newborn Hearing Screeners have the same intended use and use the same operating principle. The new device performs and is specified within all performance parameters of the predicate device.

Nonclinical Performance Data: None

Clinical Performance Data: None

Additional Information: None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 9 2003

Mr. Ronald Kohlhardt
Director, Regulatory Affairs/Quality Assurance
Natus Medical, Inc.
1501 Industrial Road
San Carlos, California 94070

Re: K030823
Trade/Device Name: ALGO® 3*i* Newborn Hearing Screener
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: March 13, 2003
Received: March 14, 2003

Dear Mr. Kohlhardt:

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), 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) you may obtain. 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,

Miriam C. Provost

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

Enclosure

510(k) Number (if known): *pending* K030823

Device Name: ALGO® 3*i* Newborn Hearing Screener

Indications for Use:

The ALGO® 3*i* Newborn Hearing Screener is a portable, 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K030823

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96