- 3 '95

ATTACHMENT D

K935160

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990, proposed revisions to 21 CFR, per FDA Interim Rule of April 28, 1992, § 807.92, Content and format of a 510(k) summary.

1. **Submitter's Information:** Dated October 28, 1993
   Natus Medical, Inc.
   1501 Industrial Road
   San Carlos, CA 94070

   Contact Person: Lisa Taylor, Marketing Manager

2. **Common or Usual Name:** Hearing Protector
   Proprietary Name: MiniMuffs$_{TM}$ Neonatal Noise Attenuators
   Product Classification: Class II
   Classification Name: Protector, Hearing (Circumaural):EN 77 EWE

3. **Predicate Device:** Crown Delta Corp. Ear Stopples, 510(k):K781907

4. **Description of Device:**
   Natus Medical Inc MiniMuffs$_{TM}$ are thermoformed long chain polyethylene domed circumaural noise attenuators with a water soluble adhesive perimeter

5. **Statement of intended use:**
   The Natus Medical Inc. MiniMuffs$_{TM}$ Neonatal Noise Attenuators are intended for use on newborns to provide reduction in the sound level reaching the newborn's ear. Reducing noise can stabilize the heart rate, decrease adverse physiological states such as oxygen desaturation, can decrease behavior states such as crying and fussing, and can lead to an increase in length of sleep.

6. **Statement of technological characteristics:**
   There are other noise attenuation devices presently on the market with the same function. They all use a physical seal with the body to stop sound waves and are made of a noise attenuation material such as filled wax, filled silicone, or thermoplastic polymer foam. MiniMuffs$_{TM}$ have the same technological characteristics and are similar in design function, and application to these noise attenuation devices and do not raise any new questions concerning safety and effectiveness. The difference in the devices is the predicate device is a moldable long chain polymer inserted into the ear canal while the MiniMuffs$_{TM}$ are a formable pre-molded long chain polymer circumaural device.

   We believe the MiniMuffs$_{TM}$ intended use and technological characteristics are Substantially Equivalent to the predicate device.

   Clinical tests on neonates using the MiniMuffs$_{TM}$ were conducted at three hospitals following a written protocol. The test results are summarized in this 510(k) and support the intended use claims. No findings of adverse effects or complications were reported in the tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1995

Lisa Taylor
Director of Marketing Development
Natus Medical, Inc.
1501 Industrial Road
San Carlos, California 94070

RE: K935160/S2
MiniMuffs Neonatal Noise Attenuators
Dated: November 29, 1994
Received: November 30, 1994
Unclassified/Procode: 77 EWE

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval) 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health