K964019

JUN 18 1997

510(k) Summary

General Information

Nellcor Puritan Bennett
10200 Valley View Road
Eden Prairie, MN 55344

Submitter's Name: Chris Hadland
Phone: (612) 941-3006
Fax Number: (612) 829-5423

Proprietary Name of the Device

Morphee Plus Alpha

Common Name of the Device

Obstructive Sleep Apnea Management System

Device Classification

Obstructive sleep apnea management systems have been classified as class II by the Anesthesiology and Respiratory Devices Panel. Devices of this type have a classification code of 73FLS, Apnea Detector (21CFR 868.2375) and 73BZD, Non-continuous Ventilator (868.5905).

Intended Use

Morphee Plus Alpha is intended to manage obstructive sleep apnea through a predetermined program of positive air pressure administered through a tube and mask.

Predicate Device Equivalence

Companion 318 Nasal CPAP System - Nellcor Purtitan Bennett
DPAP Interactive Airway Management System - SleepNet Corporation

Device Description

The Morphee Plus Alpha System consists of a line powered control unit, an air tube and a patient mask. The mask is attached to the patient covering the nose and secured with straps. The air tube attaches to the mask and the control unit allowing airflow from the control unit to the mask as well as respitory sensing by the control unit.

The control unit offers both continous (CPAP) and automatice modes. In the continuous mode, the unit functions as a standard CPAP product. The auto mode allows the control unit to adjust the airway pressure based on the patient's respiration.

Summary of Performance Testing

The Morphee Plus Alpha System was tested to national and international product safety standards for electrical safety and electromagnetic compatibility. The product was also tested for mechanical, environmental and biocompatibility.

The product met all requirements and is suitable for the intended use.

Conclusions

We conclude that the Morphee Plus Alpha System meets its stated performance specifications and meets international safety standards. The clinical indications for use are substantially equivalent to the predicate products as well as the theory of operation and basic product design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1997

Mr. Chris Hadland
Nellcor Puritan Bennett Inc.
10200 Valley View Road
Eden Prairie, Minnesota 55344

Re: K964019
Morphee Plus Alpha
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: March 17, 1997
Received: March 20, 1997

Dear Mr. Hadland:

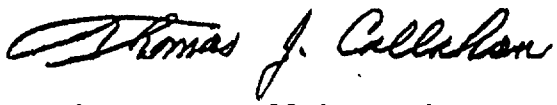
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use

Device Name:

Morphee Plus Alpha

Intended Use:

The Morphee Plus Alpha is intended to manage obstructive sleep apnea by delivering air pressure through a tube and mask. It is intended for use in either the hospital or home environment.

Concurence of CDRH, Office of Device Evaluation

510(k) number: K964019

✓ Prescription Use _ Over the Counter

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____