DEC 9 1998

K983274

Section 16. 510(k) Summary

Section 16.a Date Summary Prepared

30 November 1998

Section 16.b Company Information

Establishment:

Nellcor Puritan Bennett Inc.
4280 Hacienda Drive
Pleasanton, CA 94588

Official Correspondent:

David A.C. Green
Manager, Regulatory Affairs
Nellcor Puritan Bennett Inc.
2200 Faraday Avenue
Carlsbad, CA 92008
(760) 603-5978 (direct phone)
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Section 16.c Name of Device

Proprietary:	StarTrack Infant Graphics Monitor
Common/Usual:	Volume Monitor
Classification:	Monitoring Spirometer(§868.1850/73BZK)

Section 16.d Equivalent Devices

Substantial equivalence to the following legally marketed predicate device with the same or similar indications for use has been demonstrated by a comparison of product features as described in the labeling and promotional literature for the predicate device and the StarTrack Infant Graphics Monitor, *StarTrack*. Safety and environmental testing to accepted industry standards has been conducted as well as in-vitro testing to confirm the accuracy of StarTrack. **The predicate device is as follows:**

Bear Medical Systems Neonatal Volume Monitor, model NVM-1, K890724.

Section 16.e Device Description

The StarTrack Infant Graphics Monitor, *StarTrack* is contained in a rectangular metal enclosure measuring 9.25 inches wide by 6 inches high by 5.7 inches deep and weighing 7.2 lbs.

A front panel LCD screen enables the presentation of graphics, numeric breath data and alarm settings. User-selectable graphics screens present Flow and Volume vs Time, Pressure and Volume vs Time, Flow and Pressure vs Time, Flow / Volume Loop and Pressure / Volume Loop. Numeric breath data are Expiratory Tidal Volume, Expiratory Minute Volume, ET Tube Leak, Breath Rate and Dynamic Compliance. Alarm Settings are High Minute Volume, Low Minute Volume, High ET Tube Leak, High Breath Rate and Breath Interval.

StarTrack also provides visual and audible indicators. Alarms are divided into two categories; patient-related alarms and system-related alarms. A patient alarm causes a flashing bell to display next to the violated alarm setting. This is accompanied by an audible sound and the flashing Patient-Related Alarm LED. When the alarm condition is corrected, the audible sound ceases and the bell and LED stop flashing. These displays will turn off when the operator presses the Visual Reset button. Patient-related alarms can be silenced for sixty seconds by pressing the Alarm Silence button.

System-related alarms concern problems with the hardware, such as the sensor, sensor cable and the StarTrack electronics. System-related alarms have both visual and audible indicators. The audible indicators cannot be silenced. The System-Related alarms are Sensor Disconnect, Sensor Defect, Sensor Contaminated, AC Power Loss and System Failure.

Section 16.f Intended Use

StarTrack is intended for prescription use only for the measurement and display of breathing flow, volume and pressure as delivered from a ventilator through the patient's endotracheal tube. StarTrack is not an Apnea Monitor. The intended patient population comprises neonatal and pediatric patients who require an endotracheal tube <5.0mm I.D. and/or do not exceed a peak breathing flow of 30 L/Min directly through the ET tube. The intended environments of use comprise Hospital, Hospital-type and Intra-Hospital Transport environments. Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities such as Surgicenters, Sub-acute Centers and Special Nursing Facilities, outside of the hospital. Intra-hospital transport includes transport with a patient within the hospital or hospital-type facility.

Section 16.g Technological Characteristics

StarTrack's function is to monitor the status of the patient's airway flow, volume and pressure as delivered from a ventilator through the endotracheal (ET) tube in infants. A heated wire anemometer sensor located in series with the patient airway measures flow in the constant temperature mode. Two *heated wires* within the airway flow sensor enable the determination of flow direction as well as flow magnitude. Current passing through the heated wires maintains a constant sensor resistance and, thus, a constant sensor temperature. As flow changes, the heat loss changes and thus the heating current changes. Knowledge of this current value enables the determination of a corresponding airway flow.

StarTrack also has the capability of displaying proximal pressure information. A pressure transducer resides within StarTrack. The operator can select either StarTrack's pressure transducer or the Infant Star Ventilator's pressure transducer or the Operator can disable pressure monitoring altogether.

The embedded software contains **substantially the same software algorithm** for determining airway flow values as used on the predicate device, the Bear Medical Systems Neonatal Volume Monitor, model NVM-1, K890724.

Section 16.h Certification Statement

In accordance with the requirements of 21 CFR 807.87(j), the following certification is provided:

Nellcor Puritan Bennett Inc., believes that all data and information submitted in this Premarket Notification are truthful and accurate and no material fact has been omitted.

David A.C. Green.

David A. C. Green
Manager, Regulatory Affairs
for Nellcor Puritan Bennett Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 1998

Mr. David A. C. Green
Nellcor Puritan Bennett Inc.
2200 Faraday Avenue
Carlsbad, CA 92008

Re: K983274
StarTrack Infant Graphics Monitor
Regulatory Class: II (two)
Product Code: 73 BZK
Dated: September 16, 1998
Received: September 17, 1998

Dear Mr. Green:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4648. 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/dsma/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

510(k) Number (if known): K983274

Device Name: StarTrack Infant Graphics Monitor

Indications For Use:

The **StarTrack Infant Graphics Monitor's** intended use is the measurement and display of breathing flow, volume and pressure as delivered trough the patient's endotracheal tube. The intended patient population comprises neonatal and pediatric patients requiring an endotracheal tube ≤5.0mm I.D. and/or who do not exceed a peak breathing flow of 30 L/Min directly through the ET tube. The intended environments of use comprise Hospital, Hospital-type and Intra-Hospital Transport environments. The device is for prescription use only. Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities such as Surgicenters, Sub-acute Centers and Special Nursing Facilities, outside of the hospital. Intra-hospital transport includes transport with a patient within the hospital or hospital-type facility.

(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 Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K983274