tyco
Healthcare

Puritan Bennett

Nellcor Puritan Bennett (Melville)
303 Terry Fox Drive
Suite 400
Kanata, Ontario K2K 3J1

Tele: 613 238-1840
Fax: 613 238-1291

K030611

# 510(k) Summary

MAR 2 4 2003

## Submitter Information

Nellcor Puritan Bennett (Melville) Ltd.
400-303 Terry Fox Drive
Kanata, Ontario K2K 3J1
Canada

## Contact person

Rob Matheson
Regulatory Affairs Associate
Phone: 613-238-1840 ext. 288
Fax: 613-238-1291

Date Prepared: February 24, 2003

| | |
|---|---|
| Trade Name: | Suzanne Portable Recording system |
| Common Name: | Portable Polysomnographic Recorder |
| Classification Name: | Ventilatory Effort Recorder |
| Classification Number: | MNR-21CFR 868.2375 |

## Predicate Devices

| | | |
|---|---|---|
| K990565 | Suzanne Polysomnographic Recorder | Nellcor Puritan Bennett |
| K021090 | N-550 Pulse Oximeter | Nellcor Puritan Bennett |

## Proposed Device Description

The *Suzanne System* is composed of a data recorder that contains the electronics and software necessary to capture the physiological information of each sensor and to store this information in a Flash card or to send it to a computer via a serial communication port.

The information that can be recorded by the *Suzanne System* is :

- EEG signals
- ECG signals
- Pressure signals
- Thoracic movements

- Abdominal movements
- Breath detection (through bucco-nasal thermistor)
- Flow (through pneumotachometer)
- Envelope of ambient sound
- Body position
- Ambient light detection
- Arterial oxyhemoglobin saturation ($SpO_2$)
- Pulse rate

The signals are amplified by different amplifiers contained in elements of the system known as headboxes. When used in a home environment, the data is recorded in the flash card and the clinician uses a setup unit to check that the system works correctly and to set the recording starting time.

When used in a clinical environment, the system can be used as described above or data can be recorded to a computer with the use of a PC application software.

The system is powered by an internal battery or by a DC power supply.

## Intended Use

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

## Summary of Technological Characteristics of the Device Compared to the Legally Marketed (Unmodified) Device

The proposed Suzanne has the same technological characteristics as the above referenced predicate device, the unmodified Suzanne. The proposed version of the device has been modified by adding new pulse oximetry technology.

## Tests Performed to Support Determination of Substantial Equivalence

Clinical and non-clinical tests were performed to support the determination of substantial equivalence.

## Conclusions

The technological characteristics of the modified Suzanne and the results of clinical and non-clinical tests do not raise any new questions of safety or effectiveness when compared to the legally marketed (unmodified) device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2003

Mr. Rob Matheson
Regulatory Affairs Associate
Nellcor Puritan Bennett (Melville) Limited
400-303 Terry Fox Drive
Kanata, Ontario K2K 3J1
CANADA

Re: K030611
Trade/Device Name: Suzanne Polysomnograph System
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: February 25, 2003
Received: February 26, 2003

Dear Mr. Matheson:

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.

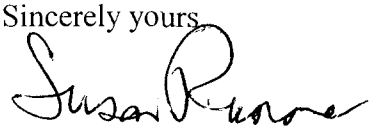
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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 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 Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Suzanne Polysomnograph System

Indications for Use:

The Nellcor Puritan Bennett Suzanne is intended for use in collecting and recording physiological data to be used in diagnosing sleep disorders.

A pediatric through adult patient population is intended for the Suzanne, which can be used in either home or hospital environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K030611