AUG 1 8 1999

K990565

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in compliance with the requirements of the Safe Medical Device Act of 1990 and CFR 807.92.

10.0 - Manufacturer Name

Nellcor Puritan Bennett (Mallinckrodt, Inc.)
2800 Northwest Blvd.
Minneapolis, MN 55441
612-694-3500

11.0 - Proprietary Name of Device

Suzanne

12.0 - Common name of Device

Ventilatory Effort Recorder

13.0 - Device Classification

Devices of this type have been classified as class II by the Anesthesiology Devices Panel. Devices of this type have a classification code of MNR, Ventilatory Effort Recorder (21 CFR 868.2375).

14.0 - 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.

15.0 - 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

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 clinican 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.

16.0 - Predicate Device Equivalence

The Nellcor Puritan Bennett *SleepWizard* is the predicate device for the Nellcor Puritan Bennett *Suzanne.*

17.0 - Performance Testing

Functional testing was performed to confirm that the *Suzanne System* is capable of meeting its stated performances specifications and that the device output is readable. The *Suzanne System* passed all tests.

Testing was performed to confirm that the *Suzanne System* complies with the November 1993 draft "Reviewer Guidance for Premarket submissions" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The *Suzanne System* passed all tests.

All software was tested in accordance with the May 29, 1998 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" published by the Office of Device Evaluation. The *Suzanne System* passed all tests.

No clinical studies were required to support a substantial equivalence determination, except for connecting the device to a healthy person and running the system to verify that readable, appropriate signals were generated.

18.0 - Conclusion

Nellcor Puritan Bennett concludes that the *Suzanne* meets its stated specifications, operates safely in its intended environment, and is effective in fulfilling its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 18 1999

Mr. Darin L. Busch
Regulatory Affairs Project Manager
Nellcor Puritan Bennett, Inc.
Sleep & Ventilation Division
2800 Northwest Blvd.
Minneapolis, MN 55441-2625

Re: K990565
Trade Name: Suzanne
Regulatory Class: II
Product Code: MNR
Dated: June 14, 1999
Received: June 16, 1999

Dear Mr. Busch:

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) 594-4586. 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 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

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 :

Suzanne Portable Polysomnograph System

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.

Concurence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

510(k) number: K990565

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990565