NELLCOR PURITAN BENNETT

K964494

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

612 941 3006
612 829 5423 Fax

FEB - 4 1997

510(k) SUMMARY

NELLCOR PURITAN BENNETT *SleepWizard*

November 7, 1996

1.0 Submitter 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
Summary Preparation Date: October 25, 1996

2.0 Device Name

Proprietary Name: Nellcor Puritan Bennett *SleepWizard*

Common Name: Sleep Disorders Data Recorder

Classification Name: MNR, Ventilatory Effort Recorder, per 21 CFR 868.2375

3.0 Predicate Device Equivalence

We are claiming substantial equivalence to the Nellcor Puritan Bennett SANDMAN, cleared for commercial distribution per K934599 and K943673.

4.0 Device Description

The system is set up by the clinician using the computer, which is connected to the Data Collector by a cable connecting to the RS232 port, or by a modem. The computer is optically isolated from the Data Collector by circuitry on the Power Board. The patient is prepared for the sleep study as described in the Clinician's Guide and Patient's Guide (Attachments 1 and 3, respectively). A Ground Electrode is connected to the Data Collector and the patient to ensure that the signals collected all are at the same ground potential. Various sensors are connected to the patient and either directly to the Data Collector or to the Extension Box which in turn is connected to the Data Collector.

During the study itself, physiologic signals are detected by the sensors. Except for the pulse oximeter, these signals are then amplified by amplifiers. Each amplifier is designed so that it dedicated to a specific sensor so that all signals are at ±3 volts after amplification. The signals are then sent to the Data Collector, where they are stored and periodically written on the Flashcard. If the Data Collector and computer are both connected to modems, the clinician can view the data on the computer screen while it is being collected from the patient.

At the conclusion of data collection (i.e., at the end of the sleep study) the Flashcard is removed from the Data Collector and inserted into the computer so that the data may be processed and printed out for analysis purposes..

5.0 Intended Use

The *SleepWizard* is intended for use in collecting, recording and displaying physiological data to be used in diagnosing sleep disorders such as obstructive sleep apnea in patients weighing over 20 kg in a clinical or home environment.

6.0 Comparison of Technological Characteristics

The device has the same technological characteristics as the predicate device, except that the *SleepWizard* is battery powered and the SANDMAN is powered by AC Mains. This clearly raises no new concerns regarding safety and effectiveness as both technologies are well understood.

7.0 Summary of Performance Testing

7.1 Functional testing was performed to confirm that *SleepWizard* is capable of meeting its stated performance specifications and that the device output is readable. *SleepWizard* passed all tests.

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

7.3 All software was tested in accordance with the August 29, 1991 "Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k)Review" published by the Office of Device Evaluation. *SleepWizard* passed all tests.

7.4 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 being generated.

8.0 Conclusions

We conclude that the *SleepWizard* meets its stated performance specifications and criteria outlined in the Reviewers Guidance publications referenced above. We conclude that the *SleepWizard* will operate safely in its intended environment and be effective in fulfilling its intended use.