JUL 16 1998

PB PURITAN BENNETT

LENEXA MEDICAL DIVISION
9728 Pflumm Road
P.O. Box 15915
Lenexa, KS 66285-5915
913-495-4800

K973004

510(k) SUMMARY

NELLCOR PURITAN BENNETT KnightStar 335

August 12, 1997

1.0 Submitter Information

Puritan-Bennett Corporation
9728 Pflumm Road
Lenexa, KS 66215

Submitter's Name:	C. Marshall Smith
Phone:	(913) 495-4845
Fax Number:	(913) 894-8764
Summary Preparation Date:	August 12, 1997

2.0 Device Name

Proprietary Name:	Nellcor Puritan Bennett KnightStar 335
Common Name:	Bi-level Pressure Support Ventilator
Classification Name:	73 MNT, Continuous Ventilator, per 21 CFR 868.5895

3.0 Predicate Device Equivalence

We are claiming substantial equivalence to the Respironics BiPAP S/T-D 30 with Detachable Control Panel 30, cleared for commercial distribution per K955324.

4.0 Device Description

The KnightStar 335 is a microprocessor-controlled flow generator capable or monitoring and controlling pressure within the patient tubing circuit. Three modes of operation are available:

- CPAP (continuous positive airway pressure
- I/E PAP (inspiratory and expiratory positive airway pressure)
- A/C (assist with control)

In the CPAP mode the system will deliver a continuous positive regulated airway pressure throughout the breath cycle (a range from 3 to 20 cmH20). In the I/E PAP mode, the system will track patient breathing effort and in response to the patient's inspiratory and expiratory efforts, provide two levels of pressure - a higher level of pressure for inhale (a range from 3 to 35 cmH20) and a lower pressure for exhale (a range from 3 to 20 cmH20). In the A/C mode, the system will deliver the same two levels of pressure as described for the I/E PAP mode with the addition of a guaranteed rate (a range from 3 to 30 breaths per minute) and I:E ratio (a range from 1:1.0 to 1:4.0).

All patient parameters are entered via the Control Module Type 1. In addition, the Control Module Type 1 provides analog signal output jacks for estimated nasal pressure, estimated patient flow and estimated tidal volume.

The Monaghan Airway Pressure Monitor is used to monitor the breathing circuit pressure and to alarm if either a preset high or low pressure is encountered.

5.0 Intended Use

The Nellcor Puritan Bennett KnightStar 335, is indicated for use in treating spontaneously breathing adult patients with obstructive sleep apnea or respiratory insufficiency in a homecare, hospital or institutional environment. In addition, when used with a Control Module Type 1 and an airway pressure monitor, it is indicated for use in treating spontaneously breathing adult patients with respiratory failure in a hospital or institutional environment.

6.0 Comparison of Technological Characteristics

Although most of the technological characteristics are the same, the KnightStar 335 is microprocessor-controlled whereas the predicate device is not. Also, the KnightStar 335 uses digital scrolling to set controls and read values, whereas the predicate device uses rotating knobs. However, no new concerns are raised regarding safety and effectiveness as both technologies are well understood.

7.0 Summary of Testing Performed

No revisions have been made to the KnightStar 335 software since the device was cleared for commercial distribution per K942210.

No additional performance testing was done inasmuch as the KnightStar 335 has not been physically changed since the 510(k), K942210 was cleared.

All applicable tests outlined in the November 1993 "Reviewer Guidance for Premarket Notification Submissions" have been performed on the KnightStar 335, as described in the original 510(k) submission, K942210. No additional testing was performed for the present 510(k) submission because no physical changes have been made since that submission was cleared.

Clinical studies have been performed , as described in the article "Evaluation of the Puritan Bennett 335 Portable Pressure Support Ventilator: Comparison with the Respironics BiPAP S/T", included as Attachment 5. Although not an extensive study, it does demonstrate that both devices can be used to treat patients with respiratory failure.

8.0 Conclusions

We have concluded that the KnightStar 335 with a Control Module Type 1 and an airway pressure monitor is substantially equivalent to the Respironics BiPAP S/T-D 30 with Detachable Control Panel 30 and that the KnightStar 335 with a Control Module Type 1 and an airway pressure monitor can be indicated for use in treating spontaneously breathing patients over 30 Kg with respiratory failure in a hospital or institutional environment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 1998

Mr. Stephen G. Theissen
Puritan-Bennett Corporation
2800 Northwest Boulevard
Minneapolis, MN 55441-2625

Re: K973004
Knightstar 335
Regulatory Class: II (two)
Product Code: 73 MNT
Dated: April 24, 1998
Received: April 29, 1998

Dear Mr. Theissen:

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

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

Enclosure

LENEXA MEDICAL DIVISION
9728 Pflumm Road
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Device Name:

Nellcor Puritan Bennett KnightStar 335

Indications for Use:

The Nellcor Puritan Bennett KnightStar 335 is indicated for use in treating spontaneously breathing patients over 30 Kg with obstructive sleep apnea or respiratory insufficiency in a homecare, hospital or institutional environment. In addition, when used with a Control Module Type 1 and an airway pressure monitor, it is indicated for use in treating spontaneously breathing patients over 30 Kg with respiratory failure in a hospital or institutional environment.

Mark Kramer

(Division Sign-Off)

Respiratory

Devices

510(k) Number K973004

✓ Prescription Use