K082966

510(k) SUMMARY

OCT 31 2008

PB 540 Ventilator

Submitter Information

Covidien, formerly Nellcor Puritan Bennett Inc.
6135 Gunbarrel Avenue
Boulder, CO 80301

Submitter's Name	Tina O'Brien Regulatory Affairs Associate II
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Device Name

Proprietary Name	PB 540 Ventilator
Common Name	Ventilator, continuous, facility use
Classification Name	CBK, Ventilator, continuous, facility use (21 CFR 868.5895)

Device Information

The PB 540 Ventilator is intended to provide continuous or intermittent mechanical ventilatory support as prescribed for patients weighing at least 5kg. The ventilator provides assist/control, SIMV, and CPAP modes of ventilation, and is intended for use in institutional, home, or transport settings. The PB 540 is not intended for use as an emergency transport ventilator.

Predicate Device Equivalence

This submission is for a modification to a previously cleared device, the Puritan Bennett Legendair XL2 Ventilator (K070899). The modified device has the following similarities to predicate device:

- has the same indicated use;
- uses the same operating principles;
- incorporates the same basic design;
- has the same useful life.

In summary, the PB 540 described in this submission is, in our opinion, substantially equivalent to the predicate device.

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification submission is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, 21 CFR § 807, Subpart E. A determination of substantial equivalency under this submission is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence in this submission shall be construed as an admission against interest under the US Patent Laws or their application by the courts..

Device Description

The PB 540 Ventilator gas delivery system is composed of a flow generator capable of supplying a sufficient range of flows and pressures that is then controlled by a three-way valve enabling piloting of the expiration valve. The flow generator is a low-inertia micro-turbine driven by a brushless electric motor and the valve is a proportional electronically driven valve.

These two actuators are controlled according to specific control algorithms by a microprocessor receiving information from the pressure and flow sensors built into the ventilator.

Indication for Use

The PB 540 is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 5 kg who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of ventilatory support, as prescribed by an attending physician:

- Positive Pressure ventilation
- Assist/Control, SIMV, or CPAP modes of ventilation
- Breath types including Volume, Pressure Control and Pressure Support.

The ventilator is suitable for use in institutional, home, and transport settings. It is not intended for use as an emergency transport ventilator.

Contraindications

This ventilator is not for use with anesthetic gases, and is not intended for use as an emergency transport ventilator.

Summary of Performance Testing

1. Functional testing confirms that the PB 540 Ventilator is capable of meeting its stated performance specifications. The device passed all tests.
2. Testing confirms that the PB 540 Ventilator complies with the applicable portions of the July 1995 "Draft Reviewer Guidance for Ventilators" published by the Division of Cardiovascular, Respiratory, and Neurological Devices. The device passed all applicable tests.
3. All software is tested in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 2005. The devices passed all tests.

Conclusions

We conclude that the PB 540 Ventilator meets the stated performance specifications and criteria referenced above and that the device and its accessories will operate safely in its intended environment and will be effective in fulfilling the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2008

Ms. Tina O'Brien
Regulatory Affairs Associate II
Covidien, Formerly Nellcor Puritan Bennett, Incorporated
6135 Gunbarrel Avenue
Boulder, Colorado 80301

Re: K082966
Trade/Device Name: PB 540 Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 3, 2008
Received: October 6, 2008

Dear Ms. O'Brien:

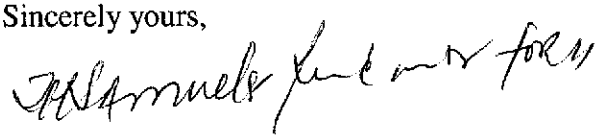
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: PB 540 Ventilator

Indications for Use:
The PB 540 Ventilator is indicated for the continuous or intermittent mechanical ventilatory support of patients weighing at least 5 kg who require mechanical ventilation. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients who require the following general types of ventilatory support, as prescribed by an attending physician:

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

510(k) Number: K082966

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)