K053388

APR 4 2006

510(k) Summary of Safety and Effectiveness

Submitted by: Puritan Bennett Corporation
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Date Prepared: Dec. 1, 2005

Trade Name: Puritan Bennett 840 Ventilator with Proportional Assist Ventilation® Plus (PAV+)

Common/Usual Name: Continuous ventilator

Classification Name: Continuous Ventilator
21 CFR 868.5895

Substantially Equivalent Devices: Puritan Bennett 840 Ventilator with Volume Ventilation Plus (VV+), K021573.

Dräger EvitaXL with SmartCare/PS Software Option, K051263

Device Description:

Proportional Assist Ventilation Plus is a software option for the Puritan Bennett 840 Ventilator that includes a spontaneous breath type called, Proportional Assist. PAV+ is designed to assist the spontaneous breathing patient with an active neural drive. Proportional Assist amplifies the patient's inspiratory effort. A control function allows the clinician to specify an amplification setting.

Intended Use

The Puritan Bennett 840 Ventilator with Proportional Assist Ventilation® Plus software option is intended for use in spontaneously breathing adult patients whose ventilator ideal body weight (IBW) is at least 25.0 kg. Patients must be intubated with either endotracheal or tracheostomy tubes of internal diameter of 6.0 mm to 10.0 mm. Patients must have satisfactory neural-ventilatory coupling, and stable, sustainable inspiratory drive. PAV+ is intended for use in hospitals and hospital-type facilities.

Technological Characteristics

As with other commercially available modes of ventilation, PAV+ provides ventilatory support according to the measured characteristics of the patient. PA is also comparable to other spontaneous breath types already available on the 840 Ventilator, such as Volume Support.

PAV+ calculates the pulmonary compliance and total pulmonary resistance of a spontaneously breathing patient and applies a proportional pressure augmentation throughout the inspiratory phase of the ventilation. The amount of pressure augmentation is determined by the clinician.

Performance Data

Performance data includes results from testing at the system level and conducting testing on controls. Clinical simulation testing was conducted to evaluate the PAV+ software in the hands of respiratory therapists. Evaluations of the software were also conducted in a hospital setting.

The performance data demonstrates substantial equivalence between the 840 Ventilator with the PAV+ software option and the legally marketed predicates; the 840 Ventilator with Volume Ventilation Plus and the Dräger EvitaXL with SmartCare/PS.

Conclusion

The technological characteristics and the results of the performance data demonstrate that the PAV+ option for the 840 Ventilator is safe and effective and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 4 2006

Mr. James Bonds
Puritan Bennett Corporation
4280 Hacienda Drive
Pleasanton, California 94588-2719

Re: K053388
Trade/Device Name: Puritan Bennett 840 Ventilator with Proportional Assist Ventilation® Plus (PAV+) Software Option
Regulation Number: 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: March 23, 2006
Received: March 24, 2006

Dear Mr. Bonds:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

Statement of Indications for Use

510(k) Number (if known): K053388

Device Name: Puritan Bennett 840 Ventilator with Proportional Assist Ventilation® Plus (PAV+) Software Option

Indications For Use:

The Puritan Bennett 840 ventilator with Proportional Assist Ventilation® Plus (PAV+) software option is intended for use in spontaneously breathing adult patients whose ventilator ideal body weight (IBW) is at least 25.0 kg. Patients must be intubated with either endotracheal or tracheostomy tubes of internal diameter of 6.0 mm to 10.0 mm. Patients must have satisfactory neural-ventilatory coupling, and stable, sustainable inspiratory drive.

PAV+ is intended for use in hospitals and hospital-type facilities.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CRF 801 Subpart D) (21 CFR 807 Subpart C)

...ology, General Hospital,
...Dental Devices

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