K063650

PURITAN-BENNETT

2200 Faraday Avenue
Carlsbad, CA 92008

Tele: 925 463-4427
Fax: 925 463-4020

510(k) Summary

FEB 15 2007

Submitted by:	Puritan-Bennett Corporation 2200 Faraday Avenue Carlsbad, CA 92008
Company Contact:	James Patrick Garvey II, RRT Regulatory Affairs Manager (925) 463-4479 (925) 463-4020 – FAX
Date Summary Prepared:	December 8, 2006
Product Name:	840 Ventilator System with Respiratory Mechanics
Common Name:	Ventilator
Classification:	Class II; Continuous Ventilator per 21 CFR §868.5895
Legally Marketed (Unmodified) Device:	• Puritan-Bennett Corp. 840 Ventilator System, K970460 • Puritan-Bennett Corp. 840 Ventilator System with Bilevel Ventilation, K984535 • Puritan-Bennett Corp. 840 Ventilator System with Neomode Option, K001646 • Puritan-Bennett Corp. 840 Ventilator System with Volume Ventilation Plus, K021573 • Puritan-Bennett Corp. 840 Ventilator System with Proportional Assist Ventilation, K053388
Predicate Devices:	• Puritan-Bennett Corp. 840 Ventilator System, K970460 • Puritan Bennett 760 Ventilator, K984379 • Puritan Bennett 7200 Ventilator, K930017 • Infrasonics Adult Star Ventilator, K922654 • Viasys Avea Ventilator, K062093

DEVICE DESCRIPTION

The Respiratory Mechanics Option enables the 840 Ventilator System to implement three new respiratory maneuvers, and permits the device to calculate and display ten additional measurements for use in the assessment of mechanical pulmonary functions of the patient's airways. The Respiratory Mechanics feature is implemented on the 840 Ventilator through additional functionality in software and by use of the existing User Interface panel. No hardware or firmware changes or additions were required. The 840 Ventilator is a dual-microprocessor controlled, critical care ventilator intended to provide continuous ventilation for neonate to adult (with NeoMode Option) or infant to adult (without NeoMode Option) patients who require either invasive ventilation or non-invasive ventilation (via face mask).

INTENDED USE

Purpose and function of the 840 Ventilator System with Respiratory Mechanics:

- The device is intended to provide continuous ventilation to patients requiring respiratory support.
- This device is intended for infant to adult patients, and for use in a wide variety of clinical conditions. The 840 Ventilator with Respiratory Mechanics is intended for use in hospital and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.
- The 840 Ventilator System with Respiratory Mechanics is intended to assist in the assessment of the patient's pulmonary function status.

Intended patient population:

- The intended patient population includes infant to adult (tidal volume 25 – 2500 mL) and neonate to adult (tidal volume 5 – 2500 mL for 840 Ventiators with NeoMode, Respiratory Measurements functions only) in patients who require continuous respiratory support.
- The intended patient population includes patients who require either invasive or non-invasive ventilation.

Intended environment of use:

- The device is intended for use in hospitals and hospital-type facilities that provide respiratory care for patients requiring respiratory support.
- The device may be used for transport within a hospital and hospital-type facility, provided compressed gas is supplied.
- The device is not to be used in the presence of flammable anesthetics.
- The device is intended for sale by or on the order of a physician only.
- This device is intended for operation by trained and qualified clinicians only and is intended for servicing by trained and qualified persons only.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The intended use of the 840 Ventilator Respiratory Mechanics is the same as that for conventional, currently marketed, critical care ventilators with similar functions. The materials and design of this device are similar to those of the predicate devices. The technical characteristics of the device modification do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 840 Ventilator with Respiratory Mechanics provides similar information as the predicate devices.

Information provided in this Special 510(k) submission provides comparative, predicate device information and describes development procedures that support the determination of substantial equivalence and assertion that the modified device is safe and effective for its intended use. Software design and development, (including verification and validation testing, test and software quality procedures) were conducted using FDA's Guidance for the Content of Pre-market Submissions for Software contained in medical devices, dated May 29, 1998, as a guidance and per internal company requirements.

In summary, Puritan-Bennett Corporation has provided information that indicates the 840 Ventilator with Respiratory Mechanics to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices, incorporating similar functionality to those that have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James Bonds
Senior Director Regulatory Affairs
Puritan Bennett Corporation
4280 Hacienda Drive
Pleasanton, California 94588

FEB 15 2007

Re: K063650
Trade/Device Name: 840 Ventilator System with Respiratory Mechanics Option
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 12, 2007
Received: January 16, 2007

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

510(k) Number (if known): _____

Device Name: 840 Ventilator System with Respiratory Mechanics Option

Indications For Use:

The 840 Ventilator with Respiratory Mechanics Option is intended to provide continuous ventilation to patients requiring respiratory support. The device is intended for patients with an Ideal Body Weight (IBW) as low as 0.5 kg (with NeoMode option) to adult, and for use in a wide variety of clinical conditions.

The 840 Ventilator with Respiratory Mechanics Options is intended for a wide range of patients ranging from neonate to adult (V_T 5-2500 mL with NeoMode) or from infant to adult (V_T 25-2500 mL).

The 840 Ventilator with Respiratory Mechanics is intended for use in hospital and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

Prescription Use: Yes (per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible], General Hospital
[illegible] Devices

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