K970460

APR 30 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Puritan-Bennett Corp.
DATE:	January 15, 1997
COMMON NAME:	Continuous Ventilator
PROPRIETARY NAME:	840 Ventilator System (840 Ventilator)
CONTACT:	Ann-Marie Butler Regulatory Affairs Project Manager Puritan-Bennett Corp. 2200 Faraday Ave. Carlsbad, CA 92008 (619) 603-5300 (phone) (619) 603-5901 (fax)
CLASSIFICATION:	Class II per 21 CFR 868.5895 Continuous Ventilator

PREDICATED DEVICES:

Puritan-Bennett Corp. is claiming substantial equivalence to the following predicate medical devices:

Predicate Device	510(k) Number	Classification
Puritan-Bennett Corp. 7200 Series Ventilator	K902506/B (7200ae)	Continuous, Critical Care Ventilator
Bear Medical Systems Inc. Bear 1000 Ventilator	K912619	Continuous, Critical Care Ventilator
Siemens Corp. Servo 300 Ventilator	K902859	Continuous, Critical Care Ventilator
Dräger Evita 4 Ventilator	K961687	Continuous, Critical Care Ventilator

1. DEVICE DESCRIPTION:

The device is a critical care ventilator intended to provide continuous ventilation for infant, pediatric, and adult patients.

The 840 Ventilator's graphic user interface (GUI) includes ventilator status keys and indicators, symbols and abbreviations with associated definitions, ventilator settings, and patient data. User input to the 840 Ventilator is provided by means of two monochrome or color touch-screen LCDs and a rotary knob. Feedback to the user is accomplished by the LCD displays and LED indicators.

The alarms associated with the 840 Ventilator meet and exceed alarm standards for modern critical care ventilators and have been developed in compliance with ISO 9703-1, ISO 9703-2, ISO 9703-3, and EN 475. These alarms are within the classification of "smart" alarms as per the ISO 9703 series of standards. The 840 Ventilator provides both non-technical (patient related) and technical (ventilator related) alarms. These alarms are arranged in a hierarchical structure with high, medium, and low urgency categories.

The 840 Ventilator includes two microprocessors: 1) the breath delivery unit (BDU) microprocessor which controls ventilation and 2) the GUI microprocessor which manages the user interface and monitors ventilator and patient data. Each microprocessor verifies that the other's instructions are being carried out properly. Using two independent microprocessors in this fashion prevents a single fault from causing a simultaneous failure of controlling and monitoring functions.

Oxygen and air connect directly to the BDU, supplying gas to each of two proportional solenoid (PSOL) valves. The optional 804 Compressor provides pressurized air to the BDU and can be used in place of wall or bottled air. The optional 802 Backup Power Source provides DC power to the BDU power supply in the event that AC power is lost.

The 840 Ventilator supplies mandatory or spontaneous breaths with a preset oxygen concentration. A mandatory (or assisted) breath can be pressure or volume controlled. Volume controlled breaths provide the patient with a preset tidal volume, peak flow, waveform, and oxygen concentration. Pressure controlled breaths provide preset pressure, inspiratory time and $\%O_2$. A spontaneous breath allows inspiratory flows of up to 200 L/min, with or without pressure support.

The 840 Ventilator offers three modes of ventilation:

- Assist/control (A/C), which consists entirely of mandatory breaths.
- Spontaneous (SPONT), which consists entirely of spontaneous breaths.
- Synchronous intermittent mandatory ventilation (SIMV), which can include both mandatory and spontaneous breaths.

The 840 Ventilator offers four breathing types:

- Volume-Controlled (VC), in which the ventilator delivers a preset tidal volume at a preset peak flow, flow waveform, and $\%O_2$.
- Pressure-Controlled (PC) in which the ventilator delivers a preset pressure, inpiratory time and $\%O_2$.
- Pressure Support (PS), in which spontaneous effort is augmented by a preset PS value and $\%O_2$.
- No Pressure Support (NONE), in which spontaneous effort is not augmented by a preset PS value, although $\%O_2$ is preset.

2. INTENDED USE:

Purpose and function of device:

- The 840 Series Ventilator is intended to provide continuous ventilation to patient's requiring respiratory support.
- This product is intended for a wide range of patients from infant to adult and for a wide variety of clinical conditions.

Intended patient population:

- The intended patient population includes infant, pediatric, and adult patients (tidal volume 25 - 2500 mL) who require continuous respiratory support.
- Intended for patient who require either invasive or non-invasive ventilation.

Intended environment of use:

- The 840 Ventilator is intended for use in hospitals and hospital type facilities which provide respiratory care for patients requiring respiratory support.
- The 840 Ventilator may be used during hospital and hospital type facility transport provided that electrical power and compressed gas are supplied.
- The 840 Ventilator is not to be used in the presence of flammable anesthetics.
- The 840 Ventilator is intended for sale by or on the order of a physician only.
- This product is intended for operation by trained and qualified clinicians only and is intended for servicing by trained and qualified persons only.

3. SUBSTANTIAL EQUIVALENCE:

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

Information provided in the 510(k) submission supports the determination of substantial equivalence. Biocompatibility analysis and laboratory testing demonstrate Puritan-Bennett's 840 Ventilator product to be safe for its intended use. Software design and development, (including verification and validation testing, test and software quality procedures) was conducted using FDA's Reviewers Guidance of Medical Device Software Submissions, 15 Dec. 1995 draft as a guidance and per internal company requirements. Environmental and electrical testing was conducted using FDA's Reviewers Guidance for Premarket Notification Submissions, Nov. 1993 draft as a guideline. Performance testing was conducted using FDA's Reviewer Guidance for Ventilators draft as a guidance and per internal, company requirements. The 840 Ventilator device design and testing are also compliant with various voluntary, international standards including: EN60601-1:1990, EN 60601-1-2:1993, CAN/CSA C22.2 No. 601-1M90:1994, UL 2601-1:1994, prEN 794-1, ISO 10651-1, and 93/42/EEC MDD.

The combined testing and analysis of results provides assurance that the device meets it's specifications and is safe and effective for its intended use.

In summary Puritan-Bennett Corp. has provided evidence that shows the 840 Ventilator to be safe and effective. This device is considered to be substantially equivalent to currently marketed devices which have been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1998

Ms. Ann-Marie Butler
Puritan-Bennett Corp.
2200 Faraday Avenue
Carlsbad, CA 92008

Re: K970460
840 Ventilator System
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: March 6, 1998
Received: April 1, 1998

Dear Ms. Butler:

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 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/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

INDICATION FOR USE

510(k) Number: K970460

Device Name: 840 Ventilator System

Indication for Use: The 840 Ventilator System is used to provide continuous ventilation to patient's requiring respiratory support. This device is used for a wide range of patients from infant to adult and for a wide variety of clinical conditions.

Prescription Use: Yes
(Per 21 CFR 801.109)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number