K984535

## SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 28 1998

**SUBMITTER:** Puritan-Bennett Corp.,
A subsidiary of Mallinckrodt Inc.

**DATE:** December 10, 1998

**COMMON NAME:** Continuous Ventilator

**PROPRIETARY NAME:** 840 Ventilator System with BiLevel Option

**CONTACT:**

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A subsidiary of Mallinckrodt Inc.
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**CLASSIFICATION:** Class II per 21 CFR 868.5895
Continuous Ventilator

**PREDICATED DEVICES:**

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

| Predicate Device | 510(k) Number | Classification |
|---|---|---|
| Puritan Bennett Corp.<br>840 Ventilator System | K970460 | Class II,<br>Continuous Ventilator<br>per 21 CFR 868.5895 |
| Puritan Bennett Corp.<br>7200 Series Ventilator | K902506B | Class II,<br>Continuous Ventilator<br>per 21 CFR 868.5895 |
| Drager<br>Evita 4 Ventilator | K961687 | Class II,<br>Continuous Ventilator<br>per 21 CFR 868.5895 |
| Siemens<br>Servo 300 Ventilator | K902859 | Class II,<br>Continuous Ventilator<br>per 21 CFR 868.5895 |

## I) DEVICE DESCRIPTION:

The 840 Ventilator System is designed and manufactured by Puritan-Bennett Corp. in Carlsbad, California, a subsidiary of Mallinckrodt Inc.

The 840 Ventilator System is a Class II device, "Continuous Ventilator", per 21 CFR Part 868.5895. This device is designated a Class I Type B equipment per IEC 601-1.

The 840 Ventilator's gas delivery system consists of two proportional solenoid valves (PSOLs) and an active expiratory valve. Previosly cleared modes of ventilation include Assist Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV), and Spontaneous (SPONT). The 840 Ventilator System supplies mandatory or spontaneous breaths with a preset level of positive end expiratory pressure (PEEP), trigger sensitivity, and oxygen concentration. A mandatory breath can be pressure- or volume-controlled, except in the optional BiLevel mode, when it is always pressure-controlled. A spontaneous breath mode allows the patient inspiratory flows of up to 200 L/min, with or without pressure support.

The 840 Ventilator modification is the addition of two new features for this device, the BiLevel Option and Inspiratory Pause. The BiLevel mode and Inspiratory Pause features were developed under the BiLevel Option project by Puritan-Bennett Corp. facility in Carlsbad, CA following the established design control procedures. Manufacture implementation of BiLevel and Inspiratory Pause will also be conducted by the Puritan-Bennett Corp., Carlsbad, CA facility in the future.

The BiLevel Option and Inspiratory Pause features are implemented on the 840 Ventilator through additional functionality in software and by using the existing User Interface panel. "BiLevel" has been added as a mode choice in the touch screen MODE menu. The INSP PAUSE key on the user interface, is activated to perform the inspiratory pause function. The pneumatic design and the electrical circuitry (apart from the User Interface printed circuit board) has remained unchanged functionally.

Puritan-Bennett Corp. asserts that a) the intended use of the 840 Ventilator with BiLevel Option, as described in its labeling, has not changed from that of the cleared device, the 840 Ventilator, and b) the fundamental scientific technology of the 840 Ventilator with BiLevel Option has not changed from that of the 840 Ventilator. The device's intended use is the same as that for standard, currently marketed critical care ventilators. The device is a dual-microprocessor controlled, critical care ventilator intended to provide continuous ventilation for infant, pediatric and adult patients who require either invasive ventilation or non-invasive ventilation (via face mask).

The BiLevel mode and Inspiratory Pause features are currently included in cleared predicate devices, providing justification for substantial equivalence.

## II. INTENDED USE:

Purpose and function of the 840 Ventilator System with BiLevel Option:

- The device is intended to provide continuous ventilation to patient's requiring respiratory support.
- This device 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 device is intended for use in hospitals and hospital type facilities which 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.

## III. SUBSTANTIAL EQUIVALENCE:

The intended use of the 840 Ventilator with BiLevel Option 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 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 BiLevel Option provides similar information as the predicate devices.

Information provided in the Special 510(k) submission provides comparative predicate device information and describes development procedures which 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) is conducted using FDA's Guidance for the Content of Premarket Submissions for Software contained in medical devices, dated May 29 1998, as a guidance and per internal company requirements.

In summary Puritan-Bennett Corp. has provided information that indicates the 840 Ventilator with BiLevel Option 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

DEC 28 1998

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

Re: K984535
840 Ventilator System with BiLevel Option
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: December 10, 1998
Received: December 21, 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 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, 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: K984535

Device Name: 840 Ventilator System with BiLevel Option

Indication for Use: The 840 Ventilator System with BiLevel Option 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)

Mark Kramer
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984535