

NOV 24 1999

K993071

SUMMARY OF SAFETY AND EFFECTIVENESS

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

DATE: September 10, 1999

COMMON NAME: Continuous Ventilator

PROPRIETARY NAME: 840 Ventilator System with ET/Tracheostomy Tube
Compensation Option

CONTACT: David A. C. Green
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Puritan-Bennett Corp.
A subsidiary of Mallinckrodt Inc.
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USA

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CLASSIFICATION: Class II per 21 CFR 868.5895
Continuous Ventilator

PREDICATED DEVICES:

Predicate devices are identified as the Puritan-Bennett 7200 Series Ventilator and the Drager Evita 4 Ventilator. Both of these predicate devices employ a pressure support feature that approximates the required compensation for the pressure drop across the ET/Tracheostomy Tube. The 840 TC is substantially equivalent to the above mentioned predicate devices.

Predicate Device	510(k) Number	Classification
Puritan-Bennett Corp. 7200 Series Ventilator	K902506B	Class II, Continuous Ventilator Per 21 CFR 868.5895
Drager Evita 4 Ventilator	K961687	Class II, Continuous Ventilator Per 21 CFR 868.5895

I DEVICE DESCRIPTION

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

The 840 Ventilator System is a "Continuous Ventilator", a Class II device, per 21 CFR Part 868.5895. This device is designated as 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. Previously 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 either pressure or volume controlled, except in the optional BiLevel mode, when it is always pressure-controlled. A spontaneous breath type allows patient inspiratory flows of up to 200 L/min, with or without pressure support.

This 840 Ventilator modification comprises the addition of a new ET/Tracheostomy Tube Compensation, "TC", feature. This feature was developed under the TC Option project at the Puritan-Bennett Corp., facility at Carlsbad, CA. Established design control procedures were followed. Manufacturing implementation of TC will also be conducted at the Puritan-Bennett Corp., Carlsbad, CA, facility in the future.

The TC feature is implemented on the 840 Ventilator through additional functionality in software and by using the existing User Interface panel. "TC" has been added as a Breath Type choice in the Touch Screen SPONT Type menu. The ventilator's pneumatic design and electrical circuitry remain functionally unchanged.

Puritan-Bennett Corp. asserts that:

- a) the intended use of the 840 Ventilator with TC 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 TC Option has not changed from that of the 840 Ventilator.

The device's intended use is the same as that of 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.

Compensation for ET/Tracheostomy Tube resistance, by provision of positive pressure support to ventilated patients, is common clinical practice, providing justification for substantial equivalence.

II. INTENDED USE:

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

The device is intended to provide continuous ventilation to patients 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 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 or hospital-type facility, provided compressed gas is supplied. The device is not intended for transport between hospitals or hospital-type facilities.

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. The 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 TC 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 this device modification do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 840 Ventilator with TC Option provides similar information as the predicate devices.

Information provided in this Special 510(k) submission provides comparative predicate device information and describes development procedures which support the determination of substantial equivalence and the assertion that the modified device is safe and effective for its intended use. Software design and development, including verification and validation testing, were 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 that the 840 Ventilator with TC Option is safe and effective. This device is considered to be substantially equivalent to currently marketed devices which have been previously cleared by FDA.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1999

Mr. David A. C. Green
Puritan-Bennett Corp.
c/o Mallinckrodt Inc.
2200 Faraday Avenue
Carlsbad, CA 92008

Re: K993071
840 Ventilator System with ET/Tracheostomy Tube
Compensation Option
Regulatory Class: II (two)
Product Code: CBK
Dated: October 26, 1999
Received: October 28, 1999

Dear Mr. Green:

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.

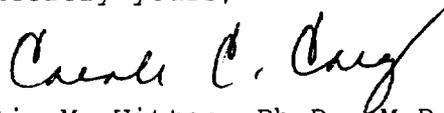
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. David A. C. Green

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,



Celia M. Witten, Ph.D., M.D.

Acting Director

Division of Cardiovascular,

Respiratory, and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K993071

Device Name: 840 Ventilator System with ET/Tracheostomy Tube Compensation, TC, Option.

Indications for Use: The 840 Ventilator System with ET/Tracheostomy Tube Compensation, TC, Option is used to provide continuous ventilation to patients 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).

Carol D. Cag

(Division Sign-Off)

for Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K993071