K964540

SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 14 1997

SUBMITTER: Puritan-Bennett Corp.

DATE: November 1, 1996

COMMON NAME: Continuous Ventilator

PROPRIETARY NAME: 740 Ventilator System (740 Ventilator)

CONTACT: Ann-Marie Butler
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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., 7200 Series Ventilator	K902506B	Class II, Continuous Ventilator per 21 CFR 868.5895
Emerson Company, J.H., Emerson 3-MV IMV	K864394	Class II Continuous Ventilator per 21 CFR 868.5895

1. DEVICE DESCRIPTION:

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

The 740 Ventilator supplies mandatory or spontaneous breaths. A mandatory (or assisted) breath provides the patient with a preset tidal volume, peak flow, waveform, and oxygen concentration. A spontaneous breath allows the patient inspiratory flows of up to 300 L/min, with or without pressure support.

The 740 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 740 Ventilator offers two breathing types:

- Volume-Controlled Ventilation (VCV), in which the ventilator delivers a preset tidal volume at a preset peak flow.
- Pressure Support Ventilation (PSV), in which spontaneous effort is augmented by a preset PSV value.

The 740 Ventilator includes two microcontrollers: 1) the breath delivery microcontroller which controls ventilation and 2) the user interface microcontroller which manages the user interface and monitors ventilator and patient data. Each microcontroller verifies that the other's instructions are being carried out properly. Using two independent microcontrollers prevents a single fault from causing a simultaneous failure of controlling and monitoring functions.

This ventilator utilizes a piston-based breath delivery system. A proprietary technique is employed in which oxygen under a regulated and constant high pressure is pulsed for precisely timed intervals via one of two solenoid valves as the piston is retracting. Piston retraction entrains room air plus the pulsed oxygen into the cylinder where the two gases mix resulting in the desired F_iO_2. The ventilator's mixing technique allows ventilation without the need for a blender, compressor, or hospital-grade wall air.

The operator communicates with the ventilator electronics via membrane keys on the user interface. An optical rotary encoder and accept key (ACCEPT) are used to change and accept settings. An LCD message display window enhances or augments visual display of alarms, settings, modes, menus, conditions, technical alerts and specialized testing procedures. Safety is enhanced through the requirement that all breath related settings be acknowledged prior to successfully changing from one breath type to another.

2. INTENDED USE:

Purpose and function of device:

- The 740 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 pediatric to adult and for a wide variety of clinical conditions.

Intended patient population:

- The intended patient population includes pediatric and adult patients (tidal volume 0.04 - 2 L) who require continuous respiratory support.
- Intended for patient who require either invasive or non-invasive ventilation.

Intended environment of use:

- The 740 Ventilator is intended for use in hospitals and hospital type facilities which provide respiratory care for patients requiring respiratory support.
- The 740 Ventilator may be used during hospital and hospiral type facility transport.
- The 740 Ventilator is not to be used in the presence of flammable anesthetics.
- The 740 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 740 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. A piston/cylinder pneumatic system is also used in the Emerson 3-MV critical care ventilator. The technical characteristics of 740 Ventilator do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 740 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 740 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 740 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 740 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

NOV 14 1997

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

Re: K964540
740 Ventilator System
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: August 15, 1997
Received: August 20, 1997

Dear Ms. Bulter:

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, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INTENDED USE, INDICATION FOR USE

The device intended use is described in sections 2.1 through 2.3 below. The device indication for use is provided separately on the next page.

Intended Use:

2.1 Purpose and function of device:

The 740 Ventilator is intended to provide continuous ventilation to patient's requiring respiratory support. This product is intended for a wide range of patients from pediatric to adult and for a wide variety of clinical conditions.

2.2 Intended patient population:

The intended patient population includes pediatric and adult patients (tidal volume 0.04 - 2 L) who require continuous respiratory support.

2.3 Intended environment of use:

The 740 Ventilator is intended for use in hospitals and hospital type facilities which provide respiratory care for patients requiring respiratory support.

The 740 Ventilator may be used during hospital and hospital type facility transport.

The 740 Ventilator is not to be used in the presence of flammable anesthetics.

The 740 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.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964540

INDICATION FOR USE

510(k) Number: _____

Device Name: 740 Ventilator System

Indication for Use: The 740 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 pediatric to adult and for a wide variety of clinical conditions.

Perscription Use: Yes
(Per 21 CFR 801.109)