K984379

DEC 10 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Nellcor Puritan Bennett Ireland, a subsidiary of Mallinckrodt Inc.,
on behalf of:	Puritan-Bennett Corp., a subsidiary of Mallinckrodt Inc.
DATE:	December 2, 1998
COMMON NAME:	Continuous Ventilator
PROPRIETARY NAME:	760 Ventilator System (760 Ventilator)
CONTACT:	Robbie Walsh, Regulatory Affairs Manager Nellcor Puritan Bennett Ireland, Mervue, Galway, Ireland. Tel: + 353 91 753771 Fax: + 353 91 770156
CLASSIFICATION:	Class II per 21 CFR 868.5895 Continuous Ventilator

PREDICATE DEVICES:

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

Predicate Device	510(k) Number	Classification
Puritan Bennett Corp., 740 Ventilator	K964540	Class II, Continuous Ventilator per 21 CFR 868.5895
Puritan Bennett Corp., 7200 Series Ventilator	K902506B	Class II, Continuous Ventilator per 21 CFR 868.5895
Puritan Bennett Corp., 840 Ventilator	K970460	Class II, Continuous Ventilator per 21 CFR 868.5895

A Device Description:

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

The 760 Ventilator is the second in a planned series of ventilators to be developed by Puritan-Bennett Corp., the "700 Series Ventilators", with the first being the 740 Ventilator. As such the 760 Ventilator encompasses all the basic functionality and modes of operation of the 740 Ventilator. The major difference between the two ventilators is that the 760 Ventilator adds Pressure Control Ventilation (PCV) as a mandatory breath type and offers adjustable rise time factor and exhalation sensitivity setting in Pressure Support Ventilation (PSV). Additionally, the 760 Ventilator also offers the ability to perform respiratory mechanics calculations and maneuvers as a standard feature using the EXPIRATORY PAUSE (expiratory pause) key to calculate auto-PEEP and the INSPIRATORY PAUSE (inspiratory pause) key to calculate patient resistance and compliance.

These modifications are implemented on the 760 Ventilator through additional functionality in software and by adding keypads on the User Interface panel. The pneumatic design, breath delivery control algorithms and the electrical circuitry (apart from the User Interface printed circuit board) have remained unchanged from 740 to 760 models.

B Intended Use:

The intended use has remained unchanged from 740 to 760 Ventilators and is provided below;

Purpose and function of device:

- The 760 Ventilator is intended to provide continuous ventilation to patients 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 760 Ventilator is intended for use in hospitals and hospital type facilities which provide respiratory care for patients requiring respiratory support.

- The 760 Ventilator may be used during hospital and hospital type facility transport
- The 760 Ventilator is not to be used in the presence of flammable anesthetics
- The 760 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.

C Substantial Equivalence

The intended use of the 760 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 the 760 Ventilator do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 760 Ventilator provides similar information as the predicate devices.

Information provided in the 510(k) submission supports the determination of substantial equivalence. Software design and development, (including verification and validation testing, test and software quality procedures) was 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. Environmental testing was conducted using FDA's Reviewers Guidance for Premarket Notification Submissions, Nov. 1993 draft as a guideline and per internal company requirements. Performance testing was conducted using the ASTM F1100-90 standard as a guidance and per internal, company requirements. The 760 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, EN 794-1 and 93/42/EEC Medical Device Directive.

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

In summary Puritan-Bennett Corp. has demonstrated the 760 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

DEC 10 1998

Ms. Robbie Walsh
Puritan-Bennett Corporation
c/o Nellcor Puritan Bennett Ireland
Mervue, Galway
Ireland

Re: K984379
760 Ventilator System
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: December 4, 1998
Received: December 7, 1998

Dear Ms. Walsh:

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: K984379

Device Name: 760 Ventilator System

Indication for Use: The 760 Ventilator System is used to provide continuous ventilation to patients 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.

Prescription Use: Yes
(Per 21 CFR 801.109)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984379