MAR 15 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

K990897

SUBMITTER:	Nellcor Puritan Bennett Ireland, a subsidiary of Mallinckrodt Inc.,
on behalf of:	Puritan-Bennett Corp., a subsidiary of Mallinckrodt Inc.
DATE:	16 March 1999
COMMON NAME:	Continuous Ventilator
PROPRIETARY NAME:	700 Series 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 two predicate medical devices:

Predicate Device	510(k) Number	Classification
Siemens Servo Ventilator 300	K902859	Class II, Continuous Ventilator per 21 CFR 868.5895
Siemens Servo Ultra Nebulizer 345	K960854	Class II, Nebulizer per 21 CFR 868.5630

A Device Description:

The device is a low-cost, critical care ventilator intended to provide continuous ventilation for pediatric and adult patients, with the provision of nebulization functionality, through use of an optional accessory, the *EasyNeb* Nebulizer.

The nebulization functionality is implemented by;
a) modifying the 700 Series software to activate a nebulizer interface which directly controls the power and operation of the *EasyNeb* Nebulizer and
b) the provision of an external nebulizer, the *EasyNeb* Nebulizer, as an optional accessory, which is intended to be used solely with the 740 and 760 ventilators.

The modification to the ventilator is the activation through software of the nebulizer port on an existing Communications interface option. This nebulizer port facilitates electrical connection of the *EasyNeb* Nebulizer to the ventilator, the operation of which is controlled completely by ventilator software. The ventilator modification in essence then is a software modification which allows control of the nebulizer power on/off, the nebulization period and mode of operation.

The *EasyNeb* Nebulizer is an ultrasonic nebulizer which is designed to deliver aerosol medications to the patient without affecting ventilator performance or patient data. It is powered and controlled by a 700 Series Ventilator, with the Communications Option installed. It contains a piezoelectric crystal that generates ultrasonic waves. The crystal's vibrations are transmitted through buffer water to a medication cup and convert the liquid medication into fine particles. The nebulizer medication cup is designed for single-patient use only, and holds up to 10 mL of medication.

B Intended Use:

The intended use is provided below;

Purpose and function of device:
- The 700 Series Ventilator is intended to provide continuous ventilation to patients requiring respiratory support.
- It offers nebulization functionality through use of an optional accessory, the *EasyNeb* Nebulizer
- 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 patients who require either invasive or non-invasive ventilation.

Intended environment of use:

- The 700 Series Ventilator is intended for use in hospitals and hospital type facilities which provide respiratory care for patients requiring respiratory support.
- The 700 Series Ventilator may be used during hospital and hospital type facility transport
- The 700 Series Ventilator is not to be used in the presence of flammable anesthetics
- The 700 Series 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.

C Substantial Equivalence

The intended use of the 700 Series Ventilator, incorporating the *EasyNeb* Nebulizer as an optional accessory, is the same as that for a standard, currently marketed critical care ventilator. The materials and design of these device are similar to those of the predicate devices. The technical characteristics of the 700 Series Ventilator do not introduce new questions regarding safety or effectiveness of critical care ventilators. Furthermore, the labeling associated with the 700 Series Ventilator and *EasyNeb* Nebulizer 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. The 700 Series Ventilator and *EasyNeb* Nebulizer 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 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 700 Series Ventilator, incorporating the *EasyNeb* Nebulizer as an optional accessory, 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

MAR 15 2000

Mr. Robbie Walsh
Nellcor Puritan Bennett Ireland
Mervue Galway
Ireland

Re: K990897
700 Series Ventilator incorporating EasyNeb Nebulizer
Regulatory Class: II (two)
Product Code: CAF, CBK
Dated: December 10, 1999
Received: December 16, 1999

Dear Mr. 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,

James E. Dillard III
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: K990897

Device Name: 700 Series Ventilator System (incorporating the *EasyNeb* Nebulizer as an optional accessory)

Indication for Use: The 700 Series 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. It also has the capability to provide nebulization through use of an optional accessory, the *EasyNeb* Nebulizer.

Prescription Use: Yes
(Per 21 CFR 801.109)

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