AUG 0 7 2002

PURITAN-BENNETT

510(k) SUMMARY: K020357

SUBMITTED BY:

Puritan-Bennett Corporation
(a subsidiary of Mallinckrodt Inc.,
a Division of Tyco Healthcare Group, LP)
4280 Hacienda Drive
Pleasanton, CA 94588

DATE: August 5, 2002

COMMON NAME: Nebulizer

PROPRIETARY NAME: *800 Series EasyNeb*

CONTACT:

Gina To
Senior Regulatory Affairs Project Manager
Puritan-Bennett Corporation
4280 Hacienda Drive
Pleasanton, CA 94588
Phone: (925) 463-4427, Fax: (925) 463-4020
email: gina.to@tycohealthcare.com

CLASSIFICATION: Class II (per 21 CFR 868.5630)
Nebulizer

PREDICATE DEVICE:

Puritan-Bennett is claiming substantial equivalence to the 700 Series Ventilator incorporating the *EasyNeb Nebulizer*, K990897.

DEVICE DESCRIPTION:

The *800 Series EasyNeb* is an ultrasonic nebulizer that is designed to deliver aerosol medications to patients being mechanically ventilated. It is powered by a 24V DC power supply and controlled by a mechanical timer. It contains a piezoelectric crystal that generates ultrasonic waves which are transmitted through buffer water to a medication cup and which convert the liquid medication into an aerosol. The nebulizer medication cup is designed for single-patient use and holds up to 10 mL of medication.

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(Continued)

INTENDED USE:

The *800 Series EasyNeb* is designed to deliver aerosol medications to mechanically-ventilated patients. It is intended for use with the Puritan Bennett Model 840 Ventilator System operating in continuous mode in ventilation (not anesthetic) breathing circuits only.

The intended patient population includes neonatal, pediatric and adult patients (tidal volume 0.005 - 2 L) who require continuous respiratory support and nebulized medication.

The *800 Series EasyNeb* is intended for use in hospitals and institutions that provide care for patients requiring respiratory support. The Model 840 Ventilator System may be used for transport within the hospital or other facility. It s intended for sale by or on the order of a physician, intended for operation by qualified clinicians only, and not to be used in the presence of flammable anesthetics.

SUBSTANTIAL EQUIVALENCE:

The *800 Series EasyNeb* is identical to the EasyNeb nebulizer that was cleared for use with the Puritan-Bennett 700 Series Ventilator under 510(k) #K990897. The only modifications are the addition of an external timer, an external power supply, and a mounting bracket.

Information provided in the 510(k) supports the determination of substantial equivalence. Environmental testing was conducted per internal company requirements using FDA's Reviewer Guidance for Premarket Notification Submissions, Nov. 1993 draft as a guideline. The *800 Series EasyNeb* device design and testing are also compliant with various voluntary, international standards including: EN60601-1:1990, EN 60601-1-2:1993, preliminary EN 13544-1 Respiratory therapy equipment – Part 1: Nebulizing systems and their components, and 93/42/EEC Medical Device Directive.

The combined testing and analysis of results provide assurance that the device meets its specifications and is safe and effective for its intended use. This device is substantially equivalent to the currently marketed *EasyNeb Nebulizer* that was previously cleared by FDA for marketing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 7 2002

Ms. Gina To
Senior Regulatory Affairs project Manager
Nellcor Puritan-Bennett, Incorporated
4280 Hacienda Drive
Pleasanton, California 94588

Re: K020357
Trade/Device Name: 800 Series EasyNeb Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 4, 2002
Received: June 5, 2002

Dear Ms. To:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020357

Device Name: Puritan Bennett *800 Series EasyNeb* Nebulizer

Indications For Use:

The *800 Series EasyNeb* is intended to serve as an accessory to the Puritan Bennett Model 840 Ventilator to provide nebulization of medications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription use -OR- ___ Over-the-counter use

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K020357