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MALLINCKRODT

Nellcor Puritan Bennett, Inc.
2800 Northwest Blvd.
Minneapolis, MN 55441

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K002686.

Submitter's Name: Nellcor Puritan Bennett, Inc. (subsidiary of Mallinckrodt, Inc.)

Submitter's Address: 2800 Northwest Boulevard, Minneapolis, MN, 55441
Contact Person: Cheryl Norton
Phone Number: (763) 694-3638
FAX Number: (763) 694-3600
Summary Date: August 25, 2000

Device Trade Name:
Achieva Ventilator

Device Classification Names:
"Continuous Ventilator" (21 CFR 868.5895, Classification Number 73 CBK)

Predicate Devices:
The Achieva Ventilator is substantially equivalent to the existing Achieva Ventilator (K990177), the Pulmonetic LTV Ventilator (K984056) and the Nellcor Puritan Bennett 840 Ventilator (K970460).

Device Description:
The Achieva Ventilator is a piston driven device which can deliver a wide range of volumes, inspiratory times, breath rates, oxygen concentrations, and PEEP levels. The Achieva has three operating modes (Assist/Control, SIMV, and Spontaneous) and six ventilation modes.

The modified Achieva Ventilator is available in three different models: Achieva, Achieva PS, and Achieva PSO_2. The base model, called Achieva, is a volume ventilator. The Achieva PS model is a volume/ pressure support ventilator with an internal modem. The Achieva PSO_2 model is a volume/ pressure support ventilator with an internal modem and an internal oxygen blender.

The modified Achieva Ventilator has software changes which add functionality to the device and change some of the existing features. The new features include the addition of Flow Acceleration, Expiratory Sensitivity, and an adjustable audible alarm volume.

The Achieva Ventilator is compatible with previously cleared Nellcor Puritan Bennett patient circuits and accessories. When AC power is unavailable, the Achieva can operate from an internal 24 VDC battery for approximately 4 hours (normal load) or an optional external battery for approximately 20 hours (normal load).

The Achieva Ventilator is also capable of downloading data to the Achieva Report Generator for purposes of displaying and archiving ventilator data with a computer.

Indications For Use:
The Achieva Ventilator is intended to provide ventilatory support for pediatric and adult patients who require positive pressure mechanical ventilation. Patients should weigh no less than 11 lbs (5 kg). The ventilator is intended for use in home, institutional, and portable settings.

Contraindications:
The Achieva Ventilator is contraindicated for use with anesthetic gases.

Nonclinical Performance:
The performance of the modified Achieva was comprehensively tested. All functions as defined in the published specifications were completely validated.

The Achieva complies with the following standards (partial compliance where noted):

- IEC 601-1 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
- IEC 601-1-2 (Medical Electrical Equipment - Part 1: General Requirements for Safety. 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests)
- UL 2601-1 (Medical Electrical Equipment, Part 1: General Requirements for Safety)
- ASTM F1100-90 (Standard Specification for Ventilators Intended for Use in Critical Care) (partial compliance)
- ASTM F1246-91 (Standard Specification for Electrically Powered Home Care Ventilators, Part 1-Positive-Pressure Ventilators and Ventilator Circuits) (partial compliance)
- ASTM F1463-93 alarm standard (partial compliance)

Clinical Performance:
Clinical testing was not performed on the device. Safety and efficacy were established through non-clinical testing.

Conclusions from Nonclinical Tests:
The Achieva performs as intended according to its performance specification. The Achieva is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2000

Ms. Cheryl Norton
Nellcor Puritan Bennett, Inc.
2800 Northwest Boulevard
Minneapolis, MN 55441

Re: K002686
Achieva Ventilator
Regulatory Class: II (two)
Product Code: 73 CBK
Dated: September 20, 2000
Received: September 21, 2000

Dear Ms. Norton:

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,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Device Name: Achieva Ventilator and Report Generator

Indications For Use:

The Achieva Ventilator is intended to provide ventilatory support for pediatric and adult patients who require positive pressure mechanical ventilation. Patients should weigh no less than 11 lbs (5 kg). The ventilator is for use in home, institutional, and portable settings.

The Achieva is contraindicated for use with anesthetic gases. This device is intended to be used on the order, and under the supervision, of a physician.

Concurence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801. 109)

510(k) number: K002686

Division of Cardiovascular & Respiratory Devices
510(k) Number K002686