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NELLCOR PURITAN BENNETT

Nellcor Puritan Bennett Inc.
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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K990177.

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

Submitter's Address: 2800 Northwest Boulevard, Minneapolis, MN, 55441
Contact Person: Cheryl Rosenberg
Phone Number: (612) 694-3638
FAX Number: (612) 694-3600
Summary Date: January 14, 1999

Device Trade Name:
Achieva Ventilator and Report Generator

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

Predicate Devices:
The *Achieva* Ventilator is substantially equivalent to both the Nellcor Puritan Bennett Model *LP10* Volume Ventilator (K903010) and the Hamilton Medical *Amadeus* Ventilator (K894316).

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 *Achieva* Ventilator is available in four different models. The *Achieva* PSx and *Achieva* PS have pressure support capability. The *Achieva* PSx, *Achieva* PS, and *Achieva* X have an internal oxygen blender. The *Achieva* PSx and *Achieva* X have an internal modem.

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 24 VDC 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 {Patients should weigh no less than 11 lbs. (5 kg)} and adult patients who require positive pressure mechanical ventilation. The ventilator is for use in home, institutional, and non-emergency transport settings.

The *Achieva* Ventilator is contraindicated for use with anesthetic gases.

The *Achieva* Report Generator software is intended to be used by healthcare professionals to supplement data obtained using established clinical procedures.

Nonclinical Performance:
The performance of the *Achieva* and its interface with the *Achieva* Report Generator was comprehensively tested (including software, electrical, mechanical, environmental and EMC). 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)

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

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Ms. Cheryl Rosenberg
Senior Regulatory Affairs Project Manager
Mallinckrodt Inc.
2800 Northwest Boulevard
Minneapolis, MN 55441-2625

Re: K990177
Nellcor Puritan Bennett Achieva Ventilator and Report Generator
Regulatory Class: II (two)
Product Code: CBK
Dated: August 25, 1999
Received: August 26, 1999

Dear Ms. Rosenberg:

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" (21CFR 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,

Joan S. Weiss for,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological 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 {Patients should weigh no less than 11 lbs. (5 kg)} and adult patients who require positive pressure mechanical ventilation. 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.

The *Achieva* Report Generator is a management and information tool, to aid in the care of patients requiring ventilatory support. The information displayed by the Report Generator software is intended to be used by healthcare professionals to supplement data obtained using established clinical procedures. The *Achieva* Report Generator allows users to download, view, and print ventilator performance data that have been stored in the ventilator's internal memory. *Achieva* Report Generator users can also capture and display a snapshot of real-time waveform data (pressure, peak flow, and volume).

Concurence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____

510(k) number: __K990177__

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990177