COVIDIEN

MAR 11 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. SUBMITTER INFORMATION:

Submitter's Name:	Covidien, LP, formerly Nellcor Puritan-Bennett Corporation
Address:	6135 Gunbarrel Avenue Boulder, CO 80301
Contact:	Jean Simon
Phone:	303-305-2435
Fax:	303-305-2212
Date of Preparation:	February 26, 2010

B. DEVICE NAME:

Trade Name(s):	840 Ventilator System with Expanded NeoMode Option
Common/Usual Name:	Continuous Ventilator
Classification Names:	Class II; Anesthesiology
CFR Reference:	§868.5895
Product Code:	CBK

C. PREDICATE DEVICE:

510(k) # / Name of Predicate Device(s):

K001646 / PB 840 Ventilator with Neomode Option

K081837 / Cardinal Health / Viasys AVEA Comprehensive Ventilator

D. DEVICE DESCRIPTION:

The PB 840 Ventilator is a dual-microprocessor-based, touch-screen controlled, critical care ventilator intended to provide continuous

ventilation for neonate to adult patients (with expanded NeoMode Option) or infant to adult patients (with no Option) who require either invasive ventilation or non-invasive ventilation.

The 840 Ventilator Expanded Neomode Option includes the software enhancements that lower the ideal body weight (IBW) from 0.5kg to 0.3kg and provides the user an option to lower the tidal volume to 2mL. The ventilator determines values for operational variables and allowable settings based on breathing circuit type and IBW. The software controls prevent inadvertent mismatching of patient size and breathing circuit type.

The 840 Ventilator Expanded Neomode Option is available as an integrated part of the 840 Ventilator or as separate software upgrade kit.

E. INDICATIONS FOR USE:

The 840 Ventilator System with Expanded NeoMode Option provides continuous ventilation to patients requiring respiratory support. The 840 Ventilator System with Expanded NeoMode Option, is intended for patients with an Ideal Body Weight (IBW) as low as 0.3 kg and for use in a wide variety of clinical conditions.

The 840 Ventilator System with Expanded NeoMode Option is intended for use in hospitals and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE STATEMENT:

The subject device, the 840 Ventilator System with Expanded NeoMode Option, has the same intended use, general design and fundamental scientific technology as the predicate devices (K001646 and K081837).

The 840 Ventilator System with Expanded NeoMode Option uses technology substantially equivalent to the CBK Family of Systems (K001646 and K081837). There are no new hazards introduced by the 840 Ventilator System with Expanded NeoMode Option as compared with the predicate devices.

G. PERFORMANCE DATA SUMMARY:

As the changes to the device were made to the software and graphic user interface only and no changes were made to the hardware or firmware, repeat electrical safety testing (IEC testing) was not warranted. Electrical safety was previously established in the PB 840 Ventilator predicate device.

The PB 840 ventilator software change had no changes to patient contacting materials. Therefore, new biocompatibility testing was not warranted.

Performance testing was conducted to ensure that the specifications of the 840 Ventilator System with Expanded NeoMode Option were met thereby demonstrating the safety and effectiveness of the subject device for its intended use.

Software validation evaluating the software changes in the 840 ventilator's Patient Settings subsystem for the expanded ranges for IBW and Tidal Volume was completed in accordance with the Guidance entitled, "General Principles of Software Validation, Final Guidance for Industry and FDA Staff", issued on January 11, 2002 and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", issued on May 11, 2005. Test results met the required acceptance criteria.

The 840 ventilator 2mL breath delivery performance was verified in accordance with applicable sections of the FDA Draft Reviewer Guidance for Ventilators. Control systems performance verification tests verified the 840 ventilator breath delivery response and accuracy met Product and Controls specification requirements.

We conclude the results of this testing support the changes to the indications for use and support continued safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jean Simon
Senior Director, Regulatory Affairs
Covidien, Formerly Nellcor Puritan Bennett, Incorporated
6135 Gunbarrel Avenue
Boulder, Colorado 80301

MAR 11 2010

Re: K092847
Trade/Device Name: 840 Ventilator System with Expanded Neomode Option
Regulation Number: 21CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: March 1, 2010
Received: March 8, 2010

Dear Ms. Simon:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ___K092847___

Device Name: 840 Ventilator System with Expanded Neomode Option

Indications for Use:

The 840 Ventilator System with Expanded NeoMode Option provides continuous ventilation to patients requiring respiratory support. The 840 Ventilator System with Expanded NeoMode Option, is intended for patients with an Ideal Body Weight (IBW) as low as 0.3 kg and for use in a wide variety of clinical conditions.

The 840 Ventilator System with Expanded NeoMode Option is intended for use in hospitals and hospital-type facilities. It may be used during hospital and hospital-type facility transport provided that electrical power and compressed gas are supplied.

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

510(k) Number: K092847

Prescription Use ____X____ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)