K131252

FEB 24 2014

510(k) Summary of Substantial Equivalence pursuant to 21 CFR 807.92

Date: May 1st, 2013

General Company Information

Submitted by:

Covidien
6135 Gunbarrel Avenue
Boulder, CO 80301

Contact:

Michael Aymami
Director Regulatory Affairs
michael.aymami@covidien.com
(303) 305-2481

Manufacturing Site:

Covidien, formerly NELLCOR
PURITAN BENNETT Ireland, Ltd
Mervue, Galway, Ireland

Registration number 8020893

Device Trade Name

Puritan Bennett™ 980 Series Ventilator System

Device Classification Name

Ventilator, continuous, facility use.

Device Classification Regulation

The Device Regulation regarding the device is a class II per 21 CFR 868.5895.

Device Product Code, CFR Section. Panel

- Product Code: CBK
- CFR Section: 21 CFR§ 868.5895
- Device Panel: Anesthesiology

Predicate Devices:

The Puritan Bennett™ 980 Series Ventilator System is substantially equivalent to the previous 840 Ventilator System from Covidien and the AVEA Ventilator from CareFusion:

- K092847 – 840 Ventilator System with Expanded NeoMode Option
- K103211 – AVEA Ventilator

Device Description:

The Puritan Bennett 980 Series Ventilator System is a dual-microprocessor-based, touch-screen controlled, critical care ventilator intended to provide continuous ventilation for neonate to adult patients who require either invasive ventilation or non-invasive ventilation. It can be used in hospitals and institutions and for intra –hospital transport applications with access to the appropriate services.

The ventilator system offers features that improve patient comfort while delivering sensitive, precise breaths to critically ill patients of any age. The product ventilates Neonatal, Pediatric, and Adult patients with predicted body weights from 0.3 kg, and with tidal volumes for mandatory volume controlled breaths from 2 mL to 2500 mL.

The ventilator is designed to help clinicians improve ventilation outcomes and quality of care for patients, and can be customized with advanced technology focused on supporting patient ventilator synchrony. A full suite of software options, safety features and accessories to fit a variety of patient needs, from infant to adult are available. Software options assist clinicians in assessing the best treatment approach for their patients at any given time by amplifying the patient's own spontaneous effort to breathe.

Indications for Use:

The Puritan Bennett™ 980 Series Ventilator System is designed for use on patient population sizes from Neonatal (NICU) through Adult who require respiratory support or mechanical ventilation and weigh a minimum of 0.3kg (0.66lb). It is suitable for service in hospitals (institutions) and intra-hospital transport to provide continuous positive pressure ventilatory support, delivered invasively or noninvasively, to patients who require the following types of ventilator support:

- Positive Pressure Ventilation, delivered invasively (via endotracheal tube or trach tube) or non-invasively (via mask or nasal prongs)
- Assist/ Control, SIMV or Spontaneous modes of ventilation

Substantial Equivalence:

The Puritan Bennett 980 Series Ventilator System is a continuous ventilator, and is substantially equivalent to the currently marketed and cleared Puritan Bennett 840 ventilator system (K092847) and the AVEA ventilator (K103211) from CareFusion.

The Puritan Bennett 840 Ventilator system has been marketed in United States for over 10 years and has been the subject of several previous premarket notifications.

Testing of the Puritan Bennett 980 Series Ventilator System has been performed to establish substantial equivalence to the listed predicate devices.

Comparison of Technological Characteristics:

The Puritan Bennett 980 Series Ventilator System is substantially equivalent to the Puritan Bennett 840 Ventilator and the AVEA ventilator. All three systems are under the same regulation and FDA product code and there are no significant differences in the indications for use.

All three devices are intended for neonatal, pediatric and adult patient populations in hospital environments have similar features and meet industry standards and performance.

The proximal flow and stand by features of the PB980 are present in the predicate AVEA device. All other PB980 features are either included in the predicate PB840 or simply represent new data or alarm display or entry systems which do not affect indications for use.

Performance Testing:

Extensive non-clinical testing was done to establish substantial equivalence of the new Puritan Bennett™ 980 Series Ventilator System to the noted predicate devices.

An extensive Verification and Validation test plan was executed to verify the design of the Puritan Bennett 980 Series Ventilator System. Over 50 units were built and made available for different aspects of Verification and Validation testing.

Verification and validation testing included:

- Reliability
- Human Factors and Usability
- Labeling validation
- Breathing System
- Alarms
- Controls Design Verification
- Software Verification
- Hardware Safety Compliance (including IEC 60601-1, IEC 60601-2 and ISO

80601)
- Electromagnetic Compliance Testing
- Electrical Verification
- Mechanical Subsystems
- Environmental Testing (Temperature/Humidity, Altitude, Vibration, Cleanability, etc.)
- Packaging Verification
- Biocompatibility Risk Analysis in conformance with ISO 10993-1

The results of non-clinical testing demonstrated that the Puritan Bennett 980 Series Ventilator System is substantially equivalent to the predicate devices. No clinical testing was necessary to show substantial equivalence.

Conclusion:

Verification and validation activities were conducted to establish the performance characteristics of the Puritan Bennett 980 Ventilator System. All testing demonstrated that the Puritan Bennett 980 Ventilator System met required design verification criteria and has acceptable performance when used in accordance with its labeling; the device is therefore suitable for its intended use. The device's intended use, operating principles, ventilation modes and performance parameters are comparable to the referenced predicate devices. Therefore, the Puritan Bennett 980 Ventilator System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 24, 2014

Covidien
Mr. Michael Aymami
Director, Regulatory Affairs
6135 Gunbarrel Avenue
Boulder, CO 80301

Re: K131252
Trade/Device Name: Puritan Bennett™ 980 Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 15, 2014
Received: January 16, 2014

Dear Mr. Aymami:

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.

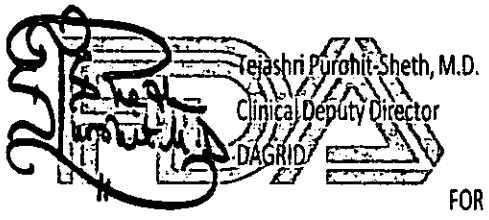
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131252

Device Name: Puritan Bennett 980 Series Ventilator System

Indications for Use:

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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 –
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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

K131252

FDA

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