DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 29, 2016

Covidien LP
Respiratory and Monitoring Solutions
Kelsey Lee
Regulatory Affairs Product Manager
6135 Gunbarrel Ave.
Boulder, Colorado 80301

Re: K151252
Trade/Device Name: Puritan Bennett™ 840 Series Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: February 25, 2016
Received: February 26, 2016

Dear Ms. Lee,

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151252

Device Name
Puritan Bennett™ 840 Series Ventilator System

Indications for Use *(Describe)*

The 840 Series Ventilator is intended to provide 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.

The 840 Series Ventilator 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510k Summary for the use of the Puritan Bennett™ 840 Series Ventilator System

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	March 22, 2016
Contact Person:	Kelsey Lee Regulatory Affairs Product Manager (303) 305-2760
Proprietary Name:	**Puritan Bennett™ 840 Series Ventilator System**
Common Name:	Continuous Ventilator
Device Classification Regulation:	21 CFR 868.5895 – Class II
Device Product Code & Panel:	CBK
Predicate Devices:	Puritan Bennett™ 840 Ventilator System with Expanded NeoMode Option**, K092847**
Reference Device:	Puritan Bennett™ 980 Series Ventilator System, **K131252**

Device Description

The PB 840 Ventilator consists of a Breath Delivery Unit (BDU, a Graphical User Interface (GUI) and a number of optional accessories, including a Compressor, a Back-Up Power Source (BPS), and three cart options. Depending on the patient ideal body weight (IBW), the appropriate patient circuit is attached to the PB 840 Ventilator System and patient. When the system is operational and connected to the appropriate utilities, the ventilator system delivers sensitive, precise breaths to critically ill patients

The Puritan Bennett (PB) 840 Ventilator System 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 PB 840 Ventilator System includes software that is intended for patients with Ideal Body Weight (IBW) as low as 0.3 kg and provides the user with tidal volume to 2 mL. The ventilator determines values for operational variables and allowable settings based on breathing types and IBW. The software controls prevent inadvertent mismatching of patient size and breathing circuit type.

Indications for Use/Intended Use
The 840 Series Ventilator is intended to provide 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.

The 840 Series Ventilator 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.

Technological Characteristics Comparison
The subject Puritan Bennett™ (PB) 840 Series Ventilator System is considered a modification of the predicate PB840 (K092847).

The technological differences between the subject and predicate PB840 are limited to the following:

- Software Enhancements
  - Communication Enhancements
  - Reduction of idle flow for Neonates
  - Update to alarm defaults for CPAP
  - Removal of redundant code

- Update apnea interval

- Hardware Enhancements
  - New BD and GUI PCBAs due to obsolescence
  - A new Pole Cart and new Compressor Cart
  - Optional four-hour 803 Backup Power Source (BPS)
  - New O2 Sensor Manufacturer
  - Fuse Upgrade on the 9.4" GUI Backlight Inverter PCBA

The subject and predicate devices have the same technological aspects:

- Intended use
- Intended Population
- Principles of Operation
- Basic ventilator design
- Manufacturing and Packaging

All other PB840 Series Ventilator System requirements and specifications remain the same

The reference device, PB980, has similar intended use, population, principles of operation and overall design. The reference device has the same oxygen sensor, alarm default for CPAP, high pressure settings and idle flow during "Idle Mode" (referred to as "Standby Mode" in the reference device).

Substantial Equivalence – Non-Clinical Evidence
The following performance data were provided in support of substantial equivalence determination:

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submission for Software Contained Medical Devices". The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could result in serious injury or death to the patient.

Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device since it required EMC enhancements based on the two new carts introduced. In addition, the new 803 Backup Power Source (BPS) for the PB840 required repeating EMC testing. The system complies with IEC 60601-1:1988 + A1:1991 + A2:1995 standard for electrical safety and IEC 60601-1-2:2014 standard for EMC. Additionally, the subject device complies with all known national differences.

Usability Testing
Usability testing was performed to ensure the new Pole Cart and Compressor Cart meet the user requirements and can be used as intended.

Substantial Equivalence – Clinical Evidence
N/A – Clinical evidence was not necessary to show substantial equivalence

Substantial Equivalence – Conclusions
Since the predicate Puritan Bennett™ (PB) 840 Ventilator with Neomode Option was cleared, this device has over time underwent both software and hardware modifications. As part of the change control process, the subject device has undergone the appropriate verification, validation and safety testing, all of which confirms that the device meets its design, performance, and safety specifications; all testing is described within the body of this submission. The performance data demonstrates that the subject device can be considered substantially equivalent to the predicate device that is currently marketed for the same intended use.