October 27, 2017

Covidien
Kelsey Lee
Regulatory Affairs Manager
6135 Gunbarrel Ave
Boulder, Colorado 80301

Re: K162738
Trade/Device Name: Puritan Bennett 980 Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: October 19, 2017
Received: October 20, 2017

Dear Kelsey Lee:

This letter corrects our substantially equivalent letter of October 27, 2017.

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 (DICE) 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 (DICE) 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K162738

Device Name
Puritan Bennett 980 Series Ventilator System

Indications for Use *(Describe)*
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 hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilatory support using medical oxygen and compressed medical air from either an internal air compressor or external air sources to deliver oxygen concentrations of 21% to 100%. Ventilatory support can be delivered invasively or non-invasively to patients who require the following types of ventilator support

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

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Puritan Bennett™ 980 Series Ventilator System.

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	October 27, 2017
Contact Person:	Kelsey Lee Regulatory Affairs Manager (303) 305-2760
Proprietary Name:	**Puritan Bennett™ 980 Series Ventilator System**
Common Name:	Ventilator, Continuous, Facility Use
Device Classification Regulation:	21 CFR 868.5895 – Class II
Device Product Code & Panel:	CBK
Predicate Devices:	**Puritan Bennett™ 980 Series Ventilator System (K131252)**
Reference Device:	**Puritan Bennett™ 840 Series Ventilator System (K151252)** **Maquet Servo-U (K151814)**

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 for patient comfort while delivering sensitive, precise breaths to critically ill patients. 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.

Indications for Use/Intended Use

The subject Puritan Bennett 980 Series Ventilator System has similar indications for use as the predicate Puritan Bennett 980 Series Ventilator System:

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 hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilatory support using medical oxygen and compressed medical air from either an internal air compressor or external air sources to deliver oxygen concentrations of 21% to 100%. Ventilatory support can be delivered invasively or non-invasively to patients who require the following types of ventilator support

- Positive Pressure Ventilation, delivered invasively (via endotracheal tube or tracheotomy tube) or non-invasively (via mask or nasal prongs)

- Assist/Control, SIMV, or Spontaneous modes of ventilation

The subject indications have been clarified to include the use of the optional internal air compressor or external air sources of gas to deliver between 21% and 100% oxygen.

Technological Characteristics Comparison
The subject Puritan Bennett 980 Ventilator System has the same intended population, principles of operation and fundamental technology as the predicate Puritan Bennett 980 Ventilator System. Additionally, the subject device is considered a derivative of the predicate device in terms of the software and hardware modifications. The subject device has the following similar technological characteristics as the predicate Maquet SERVO-U:

- Capnography Monitoring
- Exhalation Flow Sensor labelling
- Trending Option
- Pendant Mount Configuration
- Optional Internal Air Compressor

Substantial Equivalence – Non-Clinical Evidence
Substantial equivalence was shown through the following verification &validation:

- Human Factors/Usability & Design Validation
- Software Verification
- System Integration
- Controls
- Electrical Safety/EMC
- Internal Air Compressor testing, including endurance and VOCs
- Standards Compliance testing
    - AIM 7351731, rev 2.0
    - IEC 60601-1-2, 3rd edition
    - IEC ISO 60601-1, 3rd edition
    - EN ISO 80601-2-55:2011
    - EN ISO 80601-2-12: 2011
    - IEC 62366: 2007
    - IEC 60601-1-8: 2006
    - IEC 62304: 2006

The results of these non-clinical verifications & validations demonstrate that the subject Puritan Bennett™ 980 Series Ventilator System can be considered substantially equivalent to the predicates.

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

Substantial Equivalence – Conclusions
Substantial equivalence is shown similar technological characteristics, intended use, principles of operation and verification and validation. The subject Puritan Bennett™ 980 Series Ventilator System has software and hardware enhancements to maintain the intended performance of the device.

No new questions of safety and effectiveness have been raised because of these changes and addition of features. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent to the predicate devices.