Covidien, LLC
Zheng Liu
Regulatory Affairs Manager
6135 Gunbarrel Ave
Boulder, Colorado 80301

Re: K193056
Trade/Device Name: Puritan Bennett 980 Series Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: October 23, 2020
Received: October 26, 2020

Dear Ms. Liu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brandon Blakely, PhD.
Acting Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193056

Device Name
Puritan Bennett 980 Series Ventilator System
Puritan Bennett 980 Plus Ventilator

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.

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K193056

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:	09 January, 2020
Contact Person:	Zheng Liu Regulatory Affairs Manager (760) 277-4867
Proprietary Name:	Puritan Bennett™ 980 Series Ventilator System Puritan Bennett™ 980 Plus Ventilator
Common Name:	Ventilator, Continuous, Facility Use
Device Classification Regulation:	21 CFR 868.5895 – Class II
Regulation Description:	Continuous Ventilator
Device Product Code:	CBK
Primary Predicate:	Puritan Bennett™ 980 Series Ventilator System (K162738)
Reference Device:	Maquet's Servo-U/n version 2.1 (K180098)

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.

The following options are being made to the Subject Device:

- Initial release
  - Integrated Nebulizer option
  - High Flow Oxygen Therapy (HFO_2T) option
  - NIV+ Software option
  - New Monitored Parameter – P_{DRIVE}

- Modification to previously cleared feature
  - Updated IE Sync Algorithm

Indications for Use/Intended Use

The subject Puritan Bennett 980 Series Ventilator System has the same indications for use as the primary 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 Series Ventilator System has the same intended population, principles of operation, and fundamental technology as the primary predicate, the Puritan Bennett 980 Series Ventilator System (K162738). Additionally, the subject device is considered a derivative of the primary predicate in terms of software and hardware modifications, including the subject NIV+ and IE Sync triggering and cycling algorithms. The subject device has the following similar technological characteristics as the reference device, Maquet's Servo-U/n, version 2.1:

- Integrated Aerogen™* nebulizer controller Option
- High Flow Oxygen Therapy Option
- P_{DRIVE} Parameter
- Capnography Monitoring Option
- Trending Option
- Pendant Mount Configuration Option
- Integrated Compressor Option

Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence was shown through the following verification &validation:

- Human Factors/Usability & Design Validation
- Software & System Verification
- Controls Verification
- Standards Compliance testing
  - IEC ISO 60601-1, 3rd edition
  - EN ISO 80601-2-12: 1st edition
  - IEC 62366: 2007
  - IEC 60601-1-6, 3.1
  - IEC 60601-1-8: 2006
  - EN ISO 80601-2-55: 2nd edition
  - IEC 62304: 2006
  - IEC 60601-1-2, 4th edition
  - AIM 7351731, rev 2.0

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 – Biocompatibility

N/A – There were no changes in gas pathway components. Therefore, biocompatibility evaluation was not necessary to show substantial equivalence.

Substantial Equivalence – Clinical Evidence

N/A – Clinical evidence was not necessary to show substantial equivalence.

Substantial Equivalence – Conclusions

Substantial equivalence is supported by similar technological characteristics, intended use, principles of operation, and mitigation of risks through verification and validation testing. The subject Puritan Bennett™ 980 Series Ventilator System has software and hardware enhancements to maintain the intended performance of the device. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent to the predicate device.