Covidien llc
Jenny Liu
Regulatory Affairs Specialist
6F, Building 3, 2388 Chenhang Road, Minhang District
Shanghai 201114
China

Re: K202874
Trade/Device Name: Puritan Bennett Cuff Pressure Manager
Regulation Number: 21 CFR 868.5750
Regulation Name: Inflatable Tracheal Tube Cuff
Regulatory Class: Class II
Product Code: BSK
Dated: December 8, 2020
Received: December 10, 2020

Dear Jenny 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,

Todd Courtney
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202874

Device Name
Puritan Bennett™ Cuff Pressure Manager

Indications for Use *(Describe)*
The CPM is intended to continuously measure and automatically maintain the cuff pressure of an endotracheal tube or tracheostomy tube that has been set by the user/clinician during mechanical ventilation. The CPM is intended for use with adult and pediatric patients during mechanical ventilation in the listed areas:
Intensive care unit (ICU)
Recovery room
Emergency medical care
Medical emergency vehicles when the patient is being transported
During transport within and outside of the hospital

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name:	Covidien llc
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Contact Person:	Jenny Liu Regulatory Affairs Specialist Telephone: +86 15618808588 Fax: +86 21 3323-0131 Email: jenny.liu@medtronic.com
Date Prepared:	January 9, 2021

Device Name

Proprietary Name	Puritan Bennett™ Cuff Pressure Manager
Common Name	Cuff Pressure Manager
Classification Name	Cuff, Tracheal Tube, Inflatable
Device Class	Class II
Product Code	BSK
CFR Section	21 CFR 868.5750
Catalog Numbers	180-03, 180-05

Predicate Device

The Puritan Bennett™ Cuff Pressure Manager was compared to and found to be substantially equivalent to the following legally marketed products.

Proprietary Name:	IntelliCuff
Common Name:	Cuff Pressure Controller

510(k) Number: K150893 (cleared January 29, 2016)

Manufacturer Hamilton Medical AG

Device Description

The Puritan Bennett™ Cuff Pressure Manager (CPM) continuously measures and automatically maintains cuff pressure during ventilation of patients using a cuffed endotracheal tube or tracheostomy tube. It is an integrated and continuous cuff pressure control solution that secures airway management in intensive care units, recovery room and during interhospital and intrahospital transport.

It operates in range of 5-50 cm H_2O of user-set cuff pressures for various cuffed endotracheal tubes to provide suitable solutions for various clinical patient situations. The Puritan Bennett™ Cuff Pressure Manager introduces some new small features and convenient user interface to maximize safe use and usability. Both manual adjusting and one-click inflation function are provided alternatively for user's preference to start inflation. Measure mode allows user to observe the cuff pressure without device intervening before taking actions. Auto Key-lock feature help to avoid mis-operation when there's no user intervene for a long time. For inflation, room air is used and no contact to the respiratory gas system of a patient occurs. It is not intended to connect with ventilator.

The cuff pressure manager is designed with closed loop mechanism which is PI controlled, and the software level of concern is Class C/Major concern.

The Puritan Bennett™ Cuff Pressure Manager is provided non-sterile and no re-processing is required. A sterile extension tube is equipped with the Puritan Bennett™ Cuff Pressure Manager for inflating/deflating or measuring cuff pressure. The associated accessories include:

Extension Tube with filter

Rechargeable Li-ion Battery

Mounting Rack

AC/DC Adaptor

Intended Use / Indications for Use

The CPM is intended to continuously measure and automatically maintain the cuff pressure of an endotracheal tube or tracheostomy tube that has been set by the user/clinician during mechanical ventilation. The CPM is intended for use with adult and pediatric patients during mechanical ventilation in the listed areas:

Intensive care unit (ICU)

Recovery room

Emergency medical care

Medical emergency vehicles when the patient is being transported

During transport within and outside of the hospital

Comparison of Technological Characteristics with Predicate Device

The intended use and indication for use for Puritan Bennett™ Cuff Pressure Manager is equivalent to those for the predicate devices, except for limitation of use in operation room, ship, jet and helicopter.

They are similar in fundamental scientific technology in that they are all multi-patient; controller is multi-use; extension tubes are sterile (EtO), single use; inflation/deflation of an endotracheal tube or tracheostomy tube; user set pressure; software controls pressure and automatic pressure maintenance; and AC and batter power supply.

The technical differences between the Puritan Bennett™ Cuff Pressure Manager and predicate device do not raise different issues of safety or effectiveness.

The following Table 10-1 represents a summary of the major technological characteristics of the proposed and predicate devices.

Table 10-1 Comparison between proposed device and predicate device

Characteristic	Proposed Device Puritan Bennett™ Cuff Pressure Manager	Predicate Device IntelliCuff Cuff Pressure Controller (K150893)
Operation altitude	-411m to 4000m above sea level	-650 to 7,620 m above sea level
Operation temperature	0° C to 40° C / 32° F to 104° F (operating), 0° C to 50° C / 32° C to 122° F (storage)	-15° C to 50° C / 5° F to 122° F (operating), -15° C to 70° C / 5° C to 158° F (storage)
Operation relative humidity	10% to 95% noncondensing (operating) / 10% to 95% noncondensing (storage)	5% to 95% noncondensing (operating) / 5% to 95% noncondensing (storage)
Connection with ventilator	The device is not designed be connected to any mechanical ventilator.	The device can be connected to any mechanical ventilator.
Sterilization	Cuff Pressure Manager is provided non-sterile. Extension tube is provided sterile by EtO.	Controller is provided non-sterile. Cuff Pressure tube is provided sterile by EtO.
Electrical safety	Class-II Type BF in accordance with IEC 60601-1 and IEC 60601-1-12	Class-II Type BF in accordance with IEC 60601-1 and IEC 60601-1-12
Electromagnetic Compatibility	In accordance with IEC 60601-1-2	In accordance with IEC 60601-1-2
Alarm	In accordance with IEC 60601-1-8	In accordance with IEC 60601-1-8
Sensor	Two Sensors	Two Sensors
AC power input	85 to 264 VAC / 47 to 63 Hz ; 7.5 VA typical, 15 VA maximum	100 to 240 VAC / 50 to 60 Hz ± 10%; 1.25 VA typical, 3.25 VA maximum

Characteristic	Proposed Device Puritan Bennett™ Cuff Pressure Manager	Predicate Device IntelliCuff Cuff Pressure Controller (K150893)
Battery Requirement	3.6 V /2300mAh Li-ion rechargeable battery. A fully charged battery supports 4 hours operation.	AA (IEC-HR6) NiMH rechargeable 1.2 V, > 1900 mA (two pieces to support energy supply). A fully charged battery supports 5 hours operation.
Increase/Decrease Target Pressure	Yes	Yes
Measure Mode	Yes	No
Power on Self Test	Yes	Yes
Time-limited Pressure Hold	Yes	Yes
One-Click Deflation	Yes	Yes
One-Click Inflation	Yes Inflate to default target pressure when user press “One-Click Inflation” Button.	No Inflate to default target pressure the moment pressing “Power on” button.
Manual Key Lock	Yes	Yes
Auto Key Lock	Yes	No
Default inflation pressure settings	25 cm H_2O	25 cm H_2O
Pressure hold default pressure increase	5 cm H_2O	5 cm H_2O
Pressure hold maximum allowable pressure	50 cm H_2O	55 cm H_2O
Pressure hold time setting range	5 minutes to 30 minutes	5, 10 minutes
Pressure hold time factory default setting	5 minutes	5 minutes
Pressure setting range	5 to 50 cm H_2O	5 to 50 cm H_2O
Pressure unit switching	1) cm H_2O 2) hPa 3) mbar	1) cm H_2O 2) hPa 3) mbar
Resolution (setting/display)	+/-1cm H_2O	+/-1cm H_2O

Characteristic	Proposed Device Puritan Bennett™ Cuff Pressure Manager	Predicate Device IntelliCuff Cuff Pressure Controller (K150893)
Pressure Accuracy	**Pressure Accuracy (Display):** ±1.5 cm H_2O **Pressure Accuracy (Adjustment):** ±1 cm H_2O	**Pressure Accuracy (Display):** ±2 cm H_2O **Pressure Accuracy (Adjustment):** ±1 cm H_2O
Alarm Priority	**High Priority Alarm:** Low Pressure (including cuff leakage), High Pressure, Battery is depleted, Technical Errors, **Medium Priority Alarm:** Battery is very low	**High Priority Alarm:** Cuff system leakage, battery critically low, Technical fault **Medium Priority Alarm:** Pressure above set limit, cuff deflated, battery 10%, Deactivation impossible
Alarm Volume	50 dB(A) ±5 dB(A)within 1 m distance	56.5 dB(A) ± 6 dB(A) within 1 m distance
Applied pressure range in deflation mode	-45 cm H_2O	-100 cm H_2O (-100 mBar)
Pressure monitoring resolution	±0.01 cm H_2O (0.01 mbar)	±0.1 mbar
Essential Performance	The applied cuff pressure must be maintained and monitored. If it is higher or lower than the set limits (±1cm H_2O), this must be detected and the operator informed through an alarm.	The applied cuff pressure must be maintained and monitored. If it is higher or lower than the set limits(±2mbar), this must be detected and the operator informed through an alarm.
Extension Tube with Filter	Yes	Yes
Connector compatibility	Compatible with endotracheal tube (ETT) or tracheostomy tube (TT)	Compatible with endotracheal tube (ETT) or tracheostomy tube (TT)

Verification and validation activities were successfully completed. Evidence of safety and effectiveness in support of substantial equivalence were obtained from design verification and validation testing. The design differences were found to not affect safety or performance through applicable design verification activities that demonstrated conformance to applicable technical design specifications and performance requirements, applicable medical device performance standards and other non-clinical testing.

Performance Testing – Bench

1. Electrical Safety and Electromagnetic Compatibility Test

Electrical safety and EMC testing were conducted on the Puritan Bennett™ Cuff Pressure Manager. The device complies with the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- IEC 60601-1-8:2006+AMD1:2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-12:2014 Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- AIM 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

2. Function and performance Test-Cuff Pressure Manager

- Cuff Pressure Manager function and performance evaluation per technical specification
- Battery performance study on new and aged battery
- Transportation movement simulation test (vibration test, bump test and broad-band random vibration test) per EN 1789:2007+A2:2014
- Performance test on ETT of different size and material
- Benchmark test to compare with predicate device
- The performance of the closed loop design is verified per applicable clauses in IEC 60601-1-10.

3. Function and performance Test-Extension tube

- Extension tube performance evaluation per technical specification
- Luer connector connectivity test per ISO 594-1:1986 and ISO 80369-7:2016
- Stability Test
  - Accelerated aging test for 5 years shelf life per ASTM F1980:16
  - Packaging stability test per ASTM F88/F88M:2015, ASTM F1929:2015
- Sterilization validation per ISO 11135:2014 and 10993-7: 2008 AC:2009

4. Software Test

- Software Unit Test
- Software Integration Test
- User Interface Test
- Software Verification & Validation Test

5. Cybersecurity

- Cybersecurity assessment per FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”.
- Penetration test

6. Usability Test

Usability /human factor testing is performed per IEC 60601-1-6:2010+AMD1:2013 and IEC 62366-1:2015:

- Validate performance meets user need and intended use identified in customer requirement.
- Validate potential use error per risk and hazard analysis
- Validate Instructions for Use

Consensus standards utilized

Standards for Declaration of Conformity	FDA-Recognized Standard No.
ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	19-4
IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8
IEC 60601-1-8:2006+AMD1:2012 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	5-76
IEC 60601-1-12:2014 Medical electrical equipment Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	19-15
IEC 60601-1-6:2010+AMD1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	5-89
IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices	5-114
IEC 62304: 2015 Medical device software – Software life cycle processes	13-79
ISO 14971:2007 Medical devices: Application of risk management to medical devices	5-40
ANSI/AAMI ST67:2011(R2017) Sterilization of health care products—Requirements and Guidance for selecting a sterility assurance level (SAL) for products labeled “STERILE”	14-314
ISO 11135:2014 Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices	14-452
ISO 10993-7: 2008 AC:2009 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	14-408
ASTM F88/F88M:2015 Standard Test Method for Seal Strength of Flexible Barrier Materials	14-482

ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	14-484
ASTM F1980:16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	14-497
ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirement	5-117
ISO 594-1:1986 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements	6-11
ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	5-115
AIM 7351731 Rev. 2.00 2017-02-23 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers	19-30

Performance Testing – Animal

No animal data are included in this submission.

Performance Testing - Clinical

No clinical data are included in this submission.

Conclusion

The evaluation testing concludes that the Puritan Bennett™ Cuff Pressure Manager was found to be substantially equivalent to the predicate device.