December 4, 2023

Maxtec, LLC
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K231895
Trade/Device Name: Maxtec MaxBlend2+p
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR, CCL, CAP
Dated: October 31, 2023
Received: November 1, 2023

Dear Paul Dryden:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231895

Device Name

Maxtec MaxBlend 2+p

Indications for Use *(Describe)*

The Maxtec MaxBlend 2+p is intended to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen and pressure being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, subacute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required.

This is not intended as a life-supporting device or life sustaining device.

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

Date Prepared: 1-Dec-23

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Official Contact: Rebecca Hudson - QARA

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Proprietary or Trade Name: Maxtec MaxBlend2+p

Classification CFR: 21 CFR 868.5330
Classification Code: BZR
Classification Name: Mixer, Breathing Gases, Anesthesia Inhalation

Classification CFR: 21 CFR 868.1720
Classification Code: CCL
Classification Name: Analyzer, Gas, Oxygen, Gaseous-Phase

Classification CFR: 21 CFR 868.2600
Classification Code: CAP
Classification Name: Monitor, Airway Pressure

Predicate Device: Maxtec MaxBlend 2 - K161718
Secondary Predicate: MaxO2ME+p -K221734

Device Description:
The Maxtec MaxBlend 2+p is an oxygen delivery device which incorporates an air/oxygen blender, battery powered oxygen and pressure monitor, and an adjustable flowmeter, all in a single assembly. The integral air/oxygen blender provides precise mixing of medical grade air and oxygen. The flowmeter provides control of the flow rate delivered. The oxygen monitor measures the oxygen concentration from the blender's gas flow, displays these measured concentrations, and provides user selectable high and low oxygen alarms. It also allows the user to monitor pressure simultaneously using adjustable high and low alarm limits.

Indications for Use:
The Maxtec MaxBlend 2+p is designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen and pressure being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required.

This is not intended as a life-supporting device or life sustaining device.

Patient Population:
Infant, pediatric, and adult patients for MaxBlend 2+p.

Environments of use:
Hospital, sub-acute, and nursing-care facilities

We present the proposed device vs. the predicates in the **Tables** below.

Table 1 Comparison of MaxBlend 2+p to Primary Predicate

Attributes	Subject Device Maxtec MaxBlend 2+p	Primary Predicate MaxBlend 2 K161718
Product Classification	Primary - BZR Secondary – CCL New Secondary – CAP	Primary - BZR Secondary – CCL
Indications for Use	The Maxtec MaxBlend 2+p is designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen and pressure being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. This is not intended as a life-supporting device or life sustaining device.	The MaxBlend 2 and MaxBlend Lite are designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. This is not intended as a life supporting device.
New indication	Pressure monitoring	N/A See Table 2 for this feature
Environments of Use	Professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. Not for use in MRI environments	Professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. Not for use in MRI environments
Patient Population	Infant, pediatric, and adult patients	Infant, pediatric, and adult patients
Components	Oxygen monitoring Air/Oxygen Blender Flowmeter Bleed Adding pressure feature	Oxygen monitoring Air/Oxygen Blender No Flowmeter Bleed
Air/Oxygen Mixer Features		
Blender	Blender is CareFusion / Bird – K883038 or BioMed Devices – K925982	Blender is CareFusion / Bird – K883038 or BioMed Devices – K925982
Gas Supply Type **Pressure**	Air / Oxygen 30 to 75 psi	Air / Oxygen 30 to 75 psi
% Oxygen Control	21 – 100% Accuracy + 3%	21 – 100% Accuracy + 3%

Attributes	Subject Device Maxtec MaxBlend 2+p	Primary Predicate MaxBlend 2 K161718
Mixed gas stability	+ 1% oxygen	+ 1% oxygen
Flow range of Blenders	Low flow model – 0-30 Lpm High flow model – 0-70 Lpm	Low flow model – 0-30 Lpm High flow model – 0-100 Lpm
Pressure supply differential alarm	Air / oxygen pressure must be < 20 psi an alarm sounds	Air / oxygen pressure must be < 20 psi an alarm sounds
Pressure Drop	< 6 psi @ 50 psi	< 6 psi @ 50 psi
Bleed flow	3-13 Lpm at 50 psi depending upon model	3-13 Lpm at 50 psi depending upon model
Oxygen Monitor Features		
Oxygen measurement range	0-100%	0-100%
Total Accuracy	±3% Actual oxygen level over full operating temperature range	±3% Actual oxygen level over full operating temperature range
Response Time	90% of final value in approx. 15 seconds at 23°C	90% of final value in approx. 15 seconds at 23°C
Warm-up Time	None required	None required
High alarm range	16 – 100%	16 – 100%
Operating Temperature	15°C – 40°C (59°F – 104°F)	15°C – 40°C (59°F – 104°F)
Storage Temperature	-15°C – 50°C (5°F – 122°F)	-15°C – 50°C (5°F – 122°F)
Humidity	0-95% (non-condensing)	0-95% (non-condensing)
Expected use-life of sensor	1,500,000 O_2% hours (approx.. 2 years)	1,500,000 O_2% hours (approx.. 2 years)
Flowmeter Features		
Accuracy	+ 10% of indicated value when inlet pressure is 50 psi	+ 10% of indicated value when inlet pressure is 50 psi
Flow meter ranges	0 – 3 Lpm 0 – 15 Lpm 0 – 30 Lpm 0 – 70 Lpm	0 – 3 Lpm 0 – 30 Lpm 0 – 70 Lpm 0 – 100 Lpm

Attributes	Subject Device Maxtec MaxBlend 2+p	Primary Predicate MaxBlend 2 K161718
Pressure Monitor Features (adding this feature)		
Technology	Microprocessor controlled device	See Table 2
Pressure sensor type	Solid-state pressure transducer	See Table 2
Displayed information	Low pressure alarm setting High pressure alarm setting Alarm silence indicator Power supply indicator Average (mean) pressure Audible and visual alarm	See Table 2
Pressure Measurement Range	-15 to +60 cmH_2O	See Table 2
Pressure Resolution	1 cmH_2O	See Table 2
Display resolution	0.5 cm H_2O	See Table 2
Total Accuracy	+ 1 cmH_2O	See Table 2
Low alarm range	1 – 30 cmH_2O	See Table 2
High alarm range	1 – 60 cmH_2O	See Table 2
Alarm delay	3 seconds (pressure only)	See Table 2
Zero calibration	Yes	See Table 2
System interface	Disposable tubing with filter and with or without Nafion connects to tee or face mask	See Table 2
Operating Temperature	15ºC – 40ºC, 0-95% RH	See Table 2
Storage Temperature	-15ºC – 50ºC @ 95% RH	See Table 2
Atmospheric Pressure	800 – 1013 mBars	See Table 2
Power requirements	4x – AA alkaline batteries	See Table 2
Battery Life	5000 hours	See Table 2
General Information		
Standards	ANSI/AAMI/ES 60601-1 IEC 60601-1-2 IEC 60601-1-8 ISO 80601-2-55 ISO 11195	ANSI/AAMI/ES 60601-1 IEC 60601-1-2 IEC 60601-1-8 ISO 80601-2-55
Biocompatibility /Materials in Gas Pathway	Identical materials to K161718 and K221734	Externally communicating Tissue, Permanent duration
	Identical to K161718 and K221734	Materials of the Oxygen Sensor (K153659) and Blenders (K883038 and K925982) are identical

Table 2 Comparison of the proposed device vs. the Secondary Predicate MaxO2 ME+p

Attributes	Subject Device Maxtec MaxBlend 2+p	Secondary Predicate MaxO2 ME+p K221734
Product Classification	Primary – BZR Secondary – CCL New Secondary – CAP	Primary – CCL Secondary – CAP
Indications for Use	The Maxtec MaxBlend 2+p is designed to provide a continuous air/oxygen gas mixture and to continuously monitor the concentration of oxygen and pressure being delivered to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel, under the direction of a physician, in professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. This is not intended as a life-supporting device or life sustaining device.	The MaxO2 ME+p is an oxygen monitor with integrated pressure monitoring intended for continuous monitoring of the concentration of oxygen and pressure being delivered to patients ranging from newborns to adults. It can be used in the hospital and sub-acute settings.
New indication	Adding Pressure monitoring	Cleared for pressure monitoring
Environments of Use	Professional healthcare settings, i.e., hospital, sub-acute, and nursing-care facilities where the delivery and monitoring of air/oxygen mixtures is required. Not for use in MRI environments	Hospital and sub-acute settings Not for use in MRI environments
Patient Population	Infant, pediatric, and adult patients	Newborns to adults
Components	Oxygen monitoring Air/Oxygen Blender Flowmeter Bleed Pressure monitoring	Oxygen monitoring Pressure Monitoring
Pressure Monitoring Features (adding this feature)		
Technology	Microprocessor controlled device	Microprocessor controlled device
Pressure sensor type	Solid-state pressure transducer	Solid-state pressure transducer
Displayed information	Low pressure alarm setting High pressure alarm setting Alarm silence indicator Power supply indicator	Low pressure alarm setting High pressure alarm setting Alarm silence indicator Power supply indicator

Attributes	Subject Device Maxtec MaxBlend 2+p	Secondary Predicate MaxO2 ME+p K221734
	Average (mean) pressure Audible and visual alarm	Average (mean) pressure Audible and visual alarm
Pressure Measurement Range	-15 to +60 cmH_2O	-15 to +60 cmH_2O
Pressure Resolution	1 cmH_2O	1 cmH_2O
Display resolution	0.5 cm H_2O	0.5 cm H_2O
Total Accuracy	+ 1 cmH_2O	+ 1 cmH_2O
Low alarm range	1 – 30 cmH_2O	1 – 30 cmH_2O
High alarm range	1 – 60 cmH_2O	1 – 60 cmH_2O
Alarm delay	3 seconds (pressure only)	3 seconds (pressure only)
Zero calibration	Yes	Yes
System interface	Disposable tubing with filter and with or without Nafion connects to tee or face mask	Disposable tubing with filter and with or without Nafion connects to tee or face mask
Operating Temperature	15ºC – 40ºC, 0-95% RH	15ºC – 40ºC, 0-95% RH
Storage Temperature	-15ºC – 50ºC @ 95% RH	-15ºC – 50ºC @ 95% RH
Atmospheric Pressure	800 – 1013 mBars	800 – 1013 mBars
Power requirements	4x – AA alkaline batteries	4x – AA alkaline batteries
Battery Life	5000 hours	5000 hours
Oxygen Monitor Features		
Oxygen measurement range	0-100%	0-100%
Oxygen Resolution	0.1%	0.1%
Accuracy and Linearity	±1% of full scale at constant temperature, RH and pressure when calibrated at fill scale	±1% of full scale at constant temperature, RH and pressure when calibrated at fill scale
Total Accuracy	±3% Actual oxygen level over full operating temperature range	±3% Actual oxygen level over full operating temperature range
Response Time	90% of final value in approx. 15 seconds at 23ºC	90% of final value in approx. 15 seconds at 23ºC
Warm-up Time	None required	None required
High alarm range	16 – 100%	16 – 100%
Operating Temperature	15ºC – 40ºC (59ºF – 104ºF)	15ºC – 40ºC (59ºF – 104ºF)
Storage Temperature	-15ºC – 50ºC (5ºF – 122ºF)	-15ºC – 50ºC (5ºF – 122ºF)
Atmospheric Pressure	800 – 1013 mBars	800 – 1013 mBars
Humidity	0-95% (non-condensing)	0-95% (non-condensing)
Power requirements	4 – AA Alkaline batteries	4 – AA Alkaline batteries

Attributes	Subject Device Maxtec MaxBlend 2+p	Secondary Predicate MaxO2 ME+p K221734
Battery Life	Approx. 5000 hours, typical use	Approx. 5000 hours, typical use
Low Battery Indications	Battery indicator on LCD display	Battery indicator on LCD display
Sensor Type	Maxtec MAX-550E galvanic fuel cell	Maxtec MAX-550E galvanic fuel cell
Expected use-life of sensor	1,500,000 O_2% hours (approx.. 2 years)	1,500,000 O_2% hours (approx.. 2 years)
Alarm Systems	High/Low alarms, flashing yellow LEDs Nominal 975 Hz audio buzzer (IEC 60601-1-8)	High/Low alarms, flashing yellow LEDs Nominal 975 Hz audio buzzer (IEC 60601-1-8)
Low Oxygen Alarm Range	15% - 99% (>1% lower than high alarm)	15% - 99% (>1% lower than high alarm)
High Oxygen Alarm Range	16% - 100% (>1% higher than low alarm)	16% - 100% (>1% higher than low alarm)
Accuracy	Exact to display alarm value	Exact to display alarm value
Accessories	Diverter Tee adapter (15 mmm x 22 mm fittings) Pressure monitoring line Mounting brackets DC power adapter	Diverter Tee adapter (15 mmm x 22 mm fittings) Pressure monitoring line Mounting brackets DC power adapter
Air/Oxygen Mixer Features		
Blender	Blender is CareFusion / Bird – K883038 or BioMed Devices – K925982	Not applicable see Table 1
Gas Supply Type **Pressure**	Air / Oxygen 30 to 75 psi	Not applicable see Table 1
% Oxygen Control	21 – 100% Accuracy + 3%	Not applicable see Table 1
Mixed gas stability	+ 1% oxygen	Not applicable see Table 1
Flow range of Blenders	Low flow model – 0-30 Lpm High flow model – 0-100 Lpm	Not applicable see Table 1
Pressure supply differential alarm	Air / oxygen pressure must be < 20 psi an alarm sounds	Not applicable see Table 1
Pressure Drop	< 6 psi @ 50 psi	Not applicable see Table 1
Bleed flow	3-13 Lpm at 50 psi depending upon model	Not applicable see Table 1
Flowmeter Features		
Accuracy	+ 10% of indicated value when inlet pressure is 50 psi	Not applicable see Table 1
Flow meter ranges	0 – 3 Lpm 0 – 15 Lpm 0 – 30 Lpm 0 – 70 Lpm	Not applicable see Table 1

Attributes	Subject Device Maxtec MaxBlend 2+p	Secondary Predicate MaxO2 ME+p K221734
General Information		
Standards	ANSI/AAMI/ES 60601-1 IEC 60601-1-2 with RFID IEC 60601-1-8 ISO 80601-2-55 ISO 11195	ANSI/AAMI/ES 60601-1 IEC 60601-1-2 AIM RFID IEC 60601-1-8 ISO 80601-2-55
Biocompatibility Materials in Gas Pathway	Identical to K161718 and K221734 Materials of the Oxygen Sensor (K153659) and Pressure Monitoring (K221734)	Materials of the Oxygen Sensor (K153659) and Pressure Monitoring (K221734) Materials tested to applicable ISO 10993-1 and ISO 18562-1 requirements

Substantial Equivalence Discussion and Conclusion

As discussed the only new feature is the addition of the pressure monitoring feature. All other features and performance are identical to the primary and secondary predicates, we will only discuss the pressure monitoring feature being added to the subject device.

Indications for Use

The subject device, Maxtec MaxBlend 2+p,is adding the cleared feature of measuring and monitoring pressure including the disposable accessory lines. This is similar to the secondary predicate K221734 – Maxtec – MaxO2 ME+p.

However, for product classification purposes we have compared to subject device to the primary predicate which has the same primary indications for use with the added pressure monitoring feature. The primary predicate, K161718 is the MaxBlend 2 which is an air/gas blender with oxygen monitoring.

Environment of Use

The subject device, Maxtec MaxBlend 2+p has similar environments of use when compared to the primary predicate K161718 Maxtec – MaxBlend 2. There is no difference in the use environments and adding the pressure monitoring feature which has been cleared for the same use environments would raise different concerns of safety or effectiveness.

Population

The subject device, Maxtec MaxBlend 2+p has similar patient population as the primary predicate, K161718 Maxtec – MaxBlend 2. While the secondary predicate has been cleared with the pressure monitoring for newborn to adults, the subject device and its primary predicate have been cleared for infants, pediatrics and adults. The addition of the pressure monitoring feature remains within the same patient population as the secondary predicate.

Performance Specifications

The subject device, Maxtec MaxBlend 2+p, has similar performance specifications for the blender and oxygen monitoring features as the primary predicate, K161718 – Maxtec MaxBlend 2 and the pressure monitoring performance specifications as the secondary predicate, K221734 – Maxtec MaxO2 ME+p.

Non-clinical Testing

We performed a number of tests to demonstrate that the proposed device performed as intended. Testing includes:

- AAMI ANSI ES 60601-1: 2005 +A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020 Collateral standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-8: 2012 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 80601-2-55: 2018 Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 11195:2018 Gas mixers for medical use

In all cases the subject device met the standard requirements. Biocompatibility

The only new patient contacting materials are the disposable pressure tubing which are identical to the secondary predicate, K221734 – Maxtec MaxO2 ME+p. There are no changes in materials or patient contact type. These materials were evaluated in K221734 and included:

- ISO 10993-5:2009 - Cytotoxicity
- ISO 10993-10:2010 – Sensitization and Irritation

- ISO 10993-11:2017 - Material Mediated Pyrogenicity
- ISO 10993-18:2020 – Chemical Characterization with a Toxicological Risk Assessment
- ISO 18562-2:2017 – Particulate Material
- ISO 18562-3:2017 – VOC with Toxicological Risk Assessment

The patient contacting materials were found to be safe for the intended population and indications for use.

Animal
No animal testing was performed.

Clinical
No human clinical testing was performed.

Conclusion
We have performed a comparison of specifications in the above tables and found the proposed addition of the pressure monitoring feature to the subject device to be equivalent to the predicates.