



Food and Drug Administration  
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Silver Spring, MD 20993-0002

October 27, 2016

Maxtec, LLC  
c/o Paul Dryden  
Consultant  
2305 South 1070 West  
Salt Lake City, Utah 84119

Re: K161718  
Trade/Device Name: MaxBlend 2, MaxBlend Lite  
Regulation Number: 21 CFR 868.5330  
Regulation Name: Breathing Gas Mixer  
Regulatory Class: Class II  
Product Code: BZR, CCL  
Dated: September 27, 2016  
Received: September 28, 2016

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 (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,

*Tejashri Purohit-Sheth, M.D.*

Tejashri Purohit-Sheth, M.D.  
Clinical Deputy Director  
DAGRID/ODE/CDRH FOR

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

Enclosure

**Indications for Use**

510(k) Number (if known)

**K161718**

Device Name

**MaxBlend 2 and MaxBlend Lite**

Indications for Use (Describe)

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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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## 510(k) Summary

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**Sponsor Contact:** Bruce Brierley  
President  
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2305 South 1070 West  
Salt Lake City, Utah 84119  
Tel – 385-549-8070

**Applicant Contact:** Paul Dryden  
ProMedic, LLC

**Proprietary or Trade Name:** MaxBlend 2  
MaxBlend Lite

**Common/Usual Name:** Mixer, Breathing Gases, Anesthesia Inhalation

**Classification Name:** 21 CFR 868.5330  
Breathing Gas Mixer

**Product Code:** BZR, Class II  
**Additional Product Code:** CCL, Class II

**Predicate Device:** Bird, Sentry Blender – K973646

**Reference Devices:** K153659 – Maxtec MaxO<sub>2</sub>ME  
K883038 – CareFusion / Bird - Blender  
K925982 – BioMed Devices - Blender

### Device Description:

The MaxBlend family of blenders, MaxBlend 2 and MaxBlend Lite, are oxygen delivery devices which incorporate an air/oxygen blender, battery powered oxygen monitor, and an adjustable flowmeter, all in a single assembly. The 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.

The MaxBlend 2 incorporates the air/oxygen blender within its enclosure. The MaxBlend Lite may be provided with or without the blender component pre-assembled, allowing the user to install the oxygen monitor/flowmeter module, the MaxBlend Lite component, on an existing compatible blender. The addition of the MaxBlend Lite module is intended to improve the safety of an existing air/oxygen blender that is in the user's possession. Both devices use the exact same oxygen monitor sensor and electronics, MaxO<sub>2</sub>ME (K153659). Both devices use the exact same components/assemblies in the flowmeter and sensor bleed manifold which form the gas pathway to the patient. The only substantive difference is the form of the enclosure for the monitor electronics.

### Indications for Use:

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

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delivery and monitoring of air/oxygen mixtures is required. This is not intended as a life supporting device.

### **Patient Population**

The MaxBlend may be used on equipment where the patient population is infant, pediatric, and adult patients.

### **Contraindications**

There are no contraindications.

### **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.

### **Substantial Equivalence**

This section discusses how one can find the MaxBlend Family substantially equivalent to the predicate Bird Sentry Blender (K973646).

### **Indications for Use**

**Table 1** outlines the indications for use for both devices are similar, namely 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 not intended as a life supporting device.

#### **Discussion:**

One can find the subject device substantially equivalent to the predicate Bird Sentry Blender (K973646). There are no differences which raise any different questions of safety and effectiveness.

### **Environment of Use**

The environments of use are similar. The predicate device uses the term “institutional setting”; we have clarified this to be professional healthcare settings.

#### **Discussion:**

One can find the proposed device substantially equivalent to the predicate Bird Sentry Blender (K973646). There are no differences which raise any different questions of safety and effectiveness.

### **Population**

The patient population is infant to adult patients which is identical to the predicate.

#### **Discussion:**

There are no differences which raise any different questions of safety and effectiveness.

### **Performance Specifications**

The major components of the MaxBlend Family, i.e. oxygen monitoring and blender, are comprised of devices which have already been cleared for the identical indications for use, population, and environment of use. Integrating them into a single assembly for user convenience does not alter their performance. The performance specifications for the blender, oxygen monitor and their combination can be found substantially equivalent to the Bird Sentry Blender (K973646).

#### **Discussion:**

There are no differences between the predicate and the reference devices which would raise any different questions of safety and effectiveness. One can find the proposed device substantially equivalent to the predicate Bird Sentry Blender (K973646).

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**Table 1**

<b>Attributes</b>	<b>Subject Device MaxBlend 2 and MaxBlend Lite</b>	<b>Predicate Bird Sentry Blender (K973646)</b>
<b>Indications for Use</b>	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.	Bird Sentry Blender is designed to provide a continuous air/oxygen gas mixture 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 institutional environments where delivery and monitoring of air/oxygen mixtures is required.
<b>Environments of Use</b>	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	Institutional (healthcare settings) environments where the delivery and monitoring of air/oxygen mixtures is required  Not for use in MRI environments
<b>Patient Population</b>	Infant, pediatric, and adult patients	Infant, pediatric, and adult patients
<b>Components</b>	Oxygen monitoring Air/Oxygen Blender Flowmeter Bleed	Oxygen monitoring Air/Oxygen Blender No Flowmeter Bleed
<b>Weight</b>	2.4 kg	2 kg
<b>Power source of oxygen monitor</b>	4 x AA Alkaline batteries	2 x AA Alkaline batteries
<b>Air/Oxygen Mixer Features</b>		
<b>Blender</b>	Blender is CareFusion / Bird – K883038 or BioMed Devices – K925982	Bird provided blender
<b>Gas Supply Type Pressure</b>	Air / Oxygen 30 to 75 psi	Air / Oxygen 30 to 75 psi
<b>% Oxygen Control</b>	21 – 100% Accuracy $\pm$ 3%	21 – 100% Accuracy $\pm$ 3%
<b>Mixed gas stability</b>	$\pm$ 1% oxygen	$\pm$ 1% oxygen
<b>Flow range of Blenders</b>	Low flow model – 0-30 Lpm High flow model – 0-100 Lpm	Low flow model – 0-30 Lpm High flow model – 0-100 Lpm
<b>Pressure supply differential alarm</b>	Air / oxygen pressure must be < 20 psi an alarm sounds	Air / oxygen pressure must be < 20 psi an alarm sounds

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Attributes	Subject Device MaxBlend 2 and MaxBlend Lite	Predicate Bird Sentry Blender (K973646)
<b>Pressure Drop</b>	≤ 6 psi @ 50 psi	≤ 6 psi @ 50 psi
<b>Bleed flow</b>	3-13 Lpm at 50 psi depending upon model	3-13 Lpm at 50 psi depending upon model
<b>Oxygen Monitor Features</b>		
<b>Oxygen measurement range</b>	0-100%	0-100%
<b>Total Accuracy</b>	±3% Actual oxygen level over full operating temperature range	±3% Actual oxygen level over full operating temperature range
<b>Response Time</b>	90% of final value in approx. 15 seconds at 23°C	≤ 20 seconds
<b>Warm-up Time</b>	None required	None required
<b>High alarm range</b>	16 – 100%	18 – 99%
<b>Operating Temperature</b>	15°C – 40°C (59°F – 104°F)	15°C – 40°C (59°F – 104°F)
<b>Storage Temperature</b>	-15°C – 50°C (5°F – 122°F)	-15°C – 50°C (5°F – 122°F)
<b>Humidity</b>	0-95% (non-condensing)	0-100% (non-condensing)
<b>Expected use-life of sensor</b>	1,500,000 O <sub>2</sub> % hours (approx.. 2 years)	750,000 O <sub>2</sub> % hours
<b>Flowmeter Features</b>		
<b>Accuracy</b>	± 10% of indicated value when inlet pressure is 50 psi	Flowmeter is added by user and is required to function typically ± 10% of indicated value
<b>Flow meter ranges</b>	0 – 3 Lpm 0 – 30 Lpm 0 – 70 Lpm 0 – 100 Lpm	0 – 30 Lpm for Low flow 0 – 100 Lpm for High flow  Range is at the discretion of the user
<b>General Information</b>		
<b>Standards</b>	ANSI/AAMI/ES 60601-1 IEC 60601-1-2	Tested to older versions of the equivalent standards
<b>Materials in Gas Pathway</b>	Externally communicating Tissue, Permanent duration No exposure to humidified gases VOC and PM <sub>2.5</sub>	Externally communicating Tissue, Permanent duration No exposure to humidified gases
	Materials of the Oxygen Sensor (K153659) and Blenders (K883038 and K925982) are identical Materials of the flowmeter and connecting manifold tested via VOC and PM <sub>2.5</sub>	

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### Non-clinical Testing

We performed a number of tests to demonstrate that the proposed device performed as intended. Testing and a brief summary follow.

- Electrical safety and EMC testing and Mechanical and Environmental conditions
  - We utilized the following standards to evaluate the electrical safety of the device
    - ISO 80601-2-55 – Gas monitors
    - ANSI/AAMI/ES IEC 60601-1 – Electrical safety
    - MaxBlend 2 IEC-EN 60601-1-2 – EMC
    - MaxBlend Lite IEC-EN 60601-1-2 – EMC
- IEC 60601-1-8 – Alarms
  - Accuracy and alarm performance
- General Performance Test Report ISO11195 related to Standalone Blenders and ISO 15002:2008 - Flowmeter
  - This testing included applicable elements of the standard for blenders which include Reverse Gas flow, Leakage to Atmosphere, Accuracy of operation, Gas supply failure, Marking
  - Flowmeter accuracy, Leak test, environmental and mechanical conditions
- Operating and Storage Environment Report
  - Testing at high and low temperatures and humidity conditions
- Cleaning Durability
  - Durability of marking on the device was tested with standard cleaning wipes and disinfectants
- Packaging Validation
  - Testing of packaging per ISTA 2A
- MaxBlend Family Response Time Report
  - Evaluation of the oxygen sensor response time to changes in %O<sub>2</sub>
- Oxygen Compatibility Report ISO15001
  - Testing of component materials in the gas pathway for oxygen compatibility
- Usability Study Report
  - Performed usability testing to healthcare professionals

### Discussion:

In all cases the proposed device passed or meets the acceptance criteria. One can find the proposed device substantially equivalent to the predicate Bird Sentry Blender (K973646).

### Biocompatibility – Materials

All materials have been utilized and cleared under previous Maxtec products and the Blenders have also been cleared for the identical intended use. We did perform VOC and PM<sub>2.5</sub> testing for the “system” and for the other components we have provided a Material Certification statement.

Per G95-1 and ISO 10993-1:2009, these materials would be considered as:

- Externally communicating
- Tissue contact
- Duration of Use – permanent (> 30 days)

There are no materials in the gas pathway which are in contact with humidified gases. The materials in the gas pathway are only on the fresh gas delivery side of the equipment.

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The Blenders are 510(k) cleared and there is no modification or change in the materials. Maxtec purchased the blenders as finished product from the respective manufacturers. The manifold and flowmeter are the only components add to complete the “system”.

- We did perform Biocompatibility testing:
  - Gas emission VOC testing with a risk assessment of any identified chemical
    - No identifiable VOCs were detected
  - Particulate Matter (PM<sub>2.5</sub>)
    - Collected particulate was less than the acceptable standard

**Animal** - No animal testing was performed.

**Clinical** - No human clinical testing was performed.

### Discussion of Differences

There are few differences between the subject device and the predicate. They are:

- High / Low oxygen concentration alarms
  - The predicate has a range of 18 – 99% oxygen and the subject device 16 – 100%.
  - The subject device has the identical alarm range as the reference MaxO<sub>2</sub>ME (K153659) which has similar indications for use, population, and environment of use.
  - The difference in range allows for broader control. Alarms are for the convenience of the clinician and are set by the clinician.
- Pressure Drop for the blenders. Both the subject and predicate Bird Sentry (K973646) have the same specification of less than 60 psi but one is measured at 10 Lpm and the other at 40 Lpm. This specification however is identical for the Blender that has been used and cleared, so the concern of any differences is addressed through the reference blender having the identical specification of the subject device.
- Sensor expected use-life. While the expected use-life of the sensor is different between the subject device and the predicate; the expected use-life is identical to the reference MaxO<sub>2</sub>ME (K153659) incorporated into the MaxBlend family.
- Flow meter ranges. Current standalone blenders require a flowmeter to be attached in order to function. The available flowmeters that can be attached range from 200 cc/min to 100 lpm. The proposed device has been tested with a variety of flowmeter ranges: 0-3 lpm, 0-30 Lpm, 0-70 Lpm, and 0-100 Lpm. The accuracy of the flowmeters is the same +/- 10% of indicated value. The different possible flowmeter ranges is at the discretion of the user for their particular use. So long as the flowmeter range is matched to the blender range these differences do not raise any different questions of safety and effectiveness.

The differences between the predicate and the subject device are addressed when we compare the subject device to the reference devices. As noted the subject device incorporates these components in the integrated system and thus is similar to the combination of the oxygen monitor and the blender.

### **Substantial Equivalence Conclusion -**

It is sponsor’s opinion that the MaxO<sub>2</sub>ME oxygen analyzer based upon the comparative testing is substantially equivalent to the predicate device.