K092484

CardinalHealth

APR - 2 2010

510(K) Summary

510 (K) Summary as required by 21 CFR 807.92

510 (K) Submitter:

Cardinal Health 207, Inc.
Yorba Linda, CA 92887
(714) 283 – 2228

Contact Person:

Monther Abushaban
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Monther.Abushaban@CardinalHealth.com

Establishment Registration Number: 2050001

Date Prepared: April 1, 2010

Name of the Device: Heliox Low Flow Sentry Blender

Common/ usual name: Oxygen Blender for Helium/Oxygen Mixtures

Classification: The Heliox Low Flow Sentry Blender is classified as a class II device under the following classification code

Product code	CFR Section	Panel
73 BZR	21 CFR 868.5330	Anesthesiology

Predicate Device: The predicate devices are:
Sentry air/oxygen microblender (K911962)
Low Flow air/oxygen blender (K883038)
Helio2 Blender (K090781)

Device Description: The helium/oxygen and oxygen blender/monitor combines a precision helium/oxygen (79%/21%) and oxygen mixing valve with an integral battery operated oxygen concentration analyzer and user adjustable alarms.

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Intended Use:

The Heliox Low Flow Sentry Blender is designed to provide a continuous heliox/oxygen gas mixture to infant, pediatric, and adult patients. It is intended as a device to mix an 79% Helium / 21% Oxygen gas source with a 100% oxygen gas source to provide low flow mixtures containing 20% to 100% oxygen with the balance of the gas being Helium for patients who are spontaneously breathing. It is a medical device intended for use by qualified, trained personnel, under the direction of a physician, in institutional environments where the delivery and monitoring of helium/oxygen mixture is required.

Modifications to the predicate device:

The Heliox Low Flow Sentry Blender is the same device as the Sentry air/oxygen microblender (K911962). Modifications to Heliox Low Flow Sentry Blender are associated with this submittal are as follows:

- Intended use: Changed the gas mixture from air/oxygen to He- O2/oxygen mixture.
- The orifice of the poppet has been changed to address the differences in density of the helium/oxygen mixture from the density of air.
- The dial knob label artwork has been changed from analog numbers to a amplitude range.

In summary, the Heliox Low Flow Sentry Blender described in this submission is, in our opinion, substantially equivalent to the predicate device(s).

Reason for the submission:

This is a modified device with a new intended use to be marketed by Cardinal Health 207, Inc.

Summary of Technological Characteristics of Device Compared to the Predicate Device:

The Heliox Low Flow Sentry Blender is substantially equivalent in safety and effectiveness to the legally marketed (predicate) currently in distribution.

Summary of Non-clinical Testing for the Device and Conclusions:

Performance testing verified that the Heliox Low Flow Sentry Blender meets it's performance requirements that this device is substantially equivalent to medical devices currently legally marketed in the United States.

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91727 Rev A PRS Reference Numbers	Description	ER 3348 Verification Test Protocol Reference Number	Number of Units for Test	Pass or Fail
4.1.1	Dimensional Envelope	ER3348 Section 4.1.1	4	Pass
4.1.2	Weight	ER3348 Section 4.1.1	4	Pass
4.1.3	Interface (gas inlets and outlets)	ER3348 Section 4.1.1	4	Pass
4.2.1	Nominal Supply Pressure	ER3348 Section 4.1.1	4	Pass
4.2.2	Normal Operating Pressure	ER3348 Section 4.1.1	4	Pass
4.3	Environmental Withstand	Refer to Sentry Blender DHF	N/A	Pass
4.4.1	% O2 Control	ER3348 Sect. 5.2	4	Pass
4.4.2	Flow Characteristics	ER3348 Sect. 5.2	4	Pass
4.4.4	Blender Safety Features	ER3348 Sect. 5.1, 5.3	4	Pass
4.5.1	Monitor Display	ER3348 Sect. 5.1	4	Pass
4.5.1 a	Oxygen Range, Resolution, & Accuracy	ER3348 Sect. 5.1	4	Pass
4.5.1 b	Low O2 Alarm Set point	ER3348 Sect. 5.1	4	Pass
4.5.1 c	High O2 Alarm Set point	ER3348 Sect. 5.1	4	Pass
4.5.1 d	"%" Flashing during calibration	ER3348 Sect. 5.1	4	Pass
4.5.1 e	Locked Indicator	ER3348 Sect. 5.1	4	Pass
4.5.1 f	Attach Sensor	ER3348 Sect. 5.1	4	Pass
4.5.1 g	Low Battery Indicator	ER3348 Sect. 5.1	4	Pass
4.5.2	Monitor Controls	ER3348 Sect. 5.1	4	Pass
4.5.2 a	On/Off Switch	ER3348 Sect. 5.1	4	Pass

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4.5.2 b	Lock/Unlock Switch	ER3348 Sect. 5.1	4	Pass
4.5.2.1	Calibrate Button	ER3348 Sect. 5.1	4	Pass
4.5.2.2	High Set Button	ER3348 Sect. 5.1	4	Pass
4.5.2.3	Low Set Button	ER3348 Sect. 5.1	4	Pass
4.5.2.4	Alarm Silence Button	ER3348 Sect. 5.1	4	Pass
4.5.3	Alarm/Alert Indicatons	ER3348 Sect. 5.3	4	Pass
4.5.3 a	Hi O2 Concentration	ER3348 Sect. 5.3	4	Pass
4.5.3 b	Low O2 Concentration	ER3348 Sect. 5.3	4	Pass
4.5.3 c	Alarm Silence	ER3348 Sect. 5.3	4	Pass
4.5.3 d	Alarm Loudness	ER3348 Sect. 5.1	4	Pass
4.5.4	Monitor Power Source	Specified by Manufacturer (not tested)	N/A	Pass
4.5.5	Oxygen Sensor	Specified by Manufacturer (not tested)	N/A	Pass
5.1	Oxygen Blender Performance	ER3348 Sect. 5.2	4	Pass
5.2	Monitor/Analyzer Performance	ER3348 Sect. 5.3	4	Pass
5.2.1	Display, Controls, Alarms	ER3348 Sect. 5.3	4	Pass
5.2.2	System Accuracy	ER3348 Sect. 5.3	4	Pass
6.1	Labeling	ER3348 Section 4.1.1	4	Pass
6.2	Shipping Container	ER3348 Section 4.1.1	4	Pass

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness of the subject device (Heliox Low Flow Sentry Blender) as compared to predicate device.


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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Monther Abushaban
Regulatory Affairs Manager
Cardinal Health 207, Incorporated
22745 Savi Ranch Parkway
Yorba Linda, California 92887

APR - 2 2010

Re: K092484
Trade/Device Name: Heliox Low Flow Sentry Blender
Regulation Number: 21CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: II
Product Code: BZR
Dated: March 3, 2010
Received: March 31, 2010

Dear Mr. Abushaban:

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.

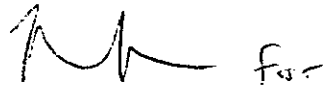
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

Device Name: Heliox Low Flow Sentry Blender

Indications for Use:

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Prescription Use_____X_____ AND/ OR Over the Counter Use:_____
(Part 21CFR 801 subpart D) (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

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