K133806

DEC 3 1 2013

510(K) Summary for M1 Capnography Mask

1. Submission Sponsor

Monitor Mask, Inc.
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Seattle
WA, 98105
USA
Phone: 877.226.1776
Contact: JW Beard MD, MBA, Founder and CEO

2. Submission Correspondent

Emergo Group, Inc.
816 Congress Avenue, Suite 1400
Austin, TX 78701
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Email: project.management@emergogroup.com

3. Date Prepared

September 20, 2013

4. Device Identification

Trade/Proprietary Name:	M1 Capnography Mask
Common/Usual Name:	oxygen/capnography mask
Classification Name:	analyzer, gas, carbon-dioxide, gaseous-phase
Classification Regulation:	§868.1400
Product Code:	CCK (primary); BYG (secondary)
Device Class:	Class II
Classification Panel:	Anesthesiology

5. Legally Marketed Predicate Device

Capnoxygen® Mask (K971229) manufactured by Medsys (Southmedic)

6. Device Description

The M1 Capnography Mask is connected to a gas source for delivering low flow oxygen through flexible tubing to the patient, and at the same time provides a means to attach a capnograph for monitoring exhaled carbon dioxide during nose and mouth breathing. The capnograph gas sample tube attaches to a standard female Luer connector on either the left or right side of the M1 Capnography Mask. The M1 Capnography Mask will initially be made available in only one size, adult large (Model #001).

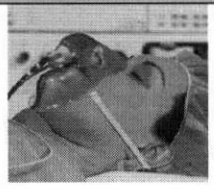
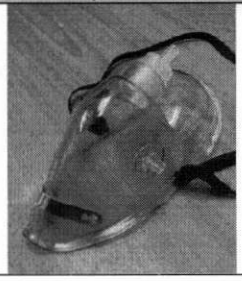
7. Indication for Use Statement

The M1 Capnography Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients. Standard oxygen tubing and two female Luer ports for gas sample line attachment are included.

8. Substantial Equivalence Discussion

The following table compares the M1 Capnography Mask to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5-A
Comparison of Characteristics

	Medsys (Southmedic)	**Monitor Mask**	**Substantial Equivalence Comparison**
Trade Name	Capnoxygen® Mask	M1 Capnography Mask	-
510(k)	K971229	Pending	-
Regulatory Classification			
Product Code	CCK	CCK	Same
Device Name	*analyzer, gas, carbon-dioxide, gaseous-phase*	*analyzer, gas, carbon-dioxide, gaseous-phase*	Same
Regulation Number	§868.1400	§868.1400	Same
Device Class	II	II	Same
Device Description			
Device Image			-
Device Description	The Capnoxygen® Mask provides a means to sample exhaled carbon dioxide via a sample tube inside the oxygen mask, during mouth and/or nose breathing. The gas sample line is	The M1 Capnography Mask is connected to a gas source for delivering low flow oxygen through flexible tubing to the patient, and at the same time provides a means to attach a	The primary difference in design between the subject and predicate device is that the M1 Capnography Mask is designed to attach more easily to a capnograph sample line thus facilitating the use of CO_2 monitoring. The subject and predicate

	connected to the Capnography monitor by a standard female Luer connector.	capnograph for monitoring exhaled carbon dioxide during nose and mouth breathing. The capnograph gas sample tube attaches to a standard female luer connector on either the left or right side of the M1 Capnography Mask.	device are essentially the same with respect to all other functional features.
Indications for Use	The Capnoxygen® Mask is a medium concentration single-use mask intended to be used for the delivery of supplemental oxygen and monitoring breathing by sampling exhaled carbon dioxide. Standard connectors for the oxygen tubing and a standard female Luer connector for the gas sample line are provided. The mask is intended to be used for monitoring non-intubated patients who are breathing spontaneously.	The M1 Capnography Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients. Standard oxygen tubing and two female Luer ports for gas sample line attachment are included.	Similar. Both the subject and predicate device are intended to supply O_2 while at the same time monitoring exhaled CO_2 in non-intubated spontaneously breathing patients. The main difference being the location of the CO_2 monitor attachment point.
Intended Use	The Capnoxygen® Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated	The M1 Capnography Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated	Similar. Both the subject and predicate device are intended to supply O_2 while at the same time monitoring exhaled CO_2 in non-intubated spontaneously breathing patients. The main difference being the location of the CO_2

	spontaneously breathing patients. Standard oxygen tubing are included.	spontaneously breathing patients. Standard oxygen tubing and two female Luer ports for gas sample line attachment are included.	monitor attachment point.
Mode of Operation	O_2 delivery to a patient through a standard O_2 supply line and simultaneous CO_2 monitoring through a gas sample line connecting the mask to a capnograph; or O_2 only delivery.	O_2 delivery to a patient through a standard O_2 supply line and simultaneous CO_2 monitoring through a gas sample line connecting the mask to a capnograph; or O_2 only delivery.	Similar. Both the subject and predicate device are intended to supply O_2 while at the same time monitoring exhaled CO_2 in non-intubated spontaneously breathing patients. The main difference being the location of the CO_2 monitor attachment point.
Body Contact	Yes, limited exposure < 24 hours duration: 1. Surface contacting device (direct skin; indirect mucosal membrane).	Yes, limited exposure < 24 hours duration: 1. Surface contacting device (direct skin; indirect mucosal membrane).	Same: Both the subject and predicate device are intended to be used for less than 24 hour of duration.
Materials	Mask (Polyvinylchloride) Oxygen line connector (Polyvinylchloride) Oxygen tubing (Polyvinylchloride) Elastic strap	Mask (Polyvinylchloride) Oxygen line connector (Polyvinylchloride) Oxygen tubing (Polyvinylchloride) Luers (Acrylic - Acrylite®) Adhesive Elastic strap Metal nose clip	Similar. Both the subject and predicate device are made from the same materials, with the exception of the Luers and adhesive used to bond them on the subject device.
Sterile	No	No	Same. Both the subject and predicate device are supplied non-sterile.
Single Use	Yes	Yes	Same. Both the subject and predicate device are for single use.
O_2 Delivery	Yes	Yes	Same. Both the subject and predicate device are used to deliver O_2 to the patient.

$ETCO_2$ Sampling	Yes	Yes	Similar. The primary difference in design between the subject and predicate device is the location of the CO_2 monitor attachment points.
Female sample line attachment Luer	Yes	Yes	The M1 Capnography Mask uses custom molded female Luers centered in both exhalation vents that serve as capnograph sample line connection points. The predicate uses a single female Luer molded into the oxygen supply line connector for sample line attachment.
Profile	Over nose/mouth	Over nose/mouth	Same. Both the subject and predicate device are designed to fit over the nose/mouth of the patient.
Face Strap	Yes	Yes	Same. Both the subject and predicate device utilize an elastic strap to secure the face mask to the patient.
Sizes	Adult - Infant	Adult Large (Model #001)	The subject device is offered in one size (adult large) while the predicate device is offered in sizes from adult – pediatric.
Biocompatibility Testing			
ISO 10993-1	Yes	Yes	The M1 Capnography Mask was subjected to biocompatibility testing in accordance with the applicable parts of ISO 10993-1.
Performance Testing			
ISO 594-2	Not known	Yes	The M1 Capnography Mask was subjected to performance testing in accordance with ISO 594-2 and passed. It is

			not known if the predicate device was subjected to such testing.
CO_2 measurement performance	Yes	Yes	The M1 Capnography mask and the predicate were subjected to side-by-side bench testing and found to be functionally equivalent in the detection of CO_2.

9. Non-Clinical Performance Data

As part of demonstrating the safety and effectiveness of its M1 Capnography Mask and in showing substantial equivalence to the predicate device that is the subject to this 510(k) submission, Monitor Mask, Inc. subjected its device to a wide range of testing that are applicable to oxygen/Capnography masks. In some instances testing was performed independent of the predicate device, while in other cases testing was performed in a side-by-side manner against the predicate device.

The M1 Capnography Mask meets all the requirements for biocompatibility, functional performance and simulated use and these testing results confirm that the design outputs meet the design inputs and user specification requirements for the device. The M1 Capnography Mask successfully passed all testing stated below by the acceptable results obtained.

- Device Shelf Life per ASTM F 1980-07
- Device Packaging and Distribution per ASTM D 4169-09
- Device Functional Performance per ISO 594-2
- Device Biocompatibility per ISO 10993-1
- Simulated Use Testing per Monitor Mask Internal Company Protocol
- Mechanical Strength Testing of Bonded Luer to Device

10. Clinical Performance Data

There was no clinical testing required to support the M1 Capnography Mask as the indications for use is equivalent to the predicate device. These types of devices, including the predicate device, have been on the market for many years with a proven safety and efficacy record for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the M1 Capnography Mask, and its safety and effectiveness.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared device, or has the same intended use and different technological characteristics, but it can be demonstrated that the new device is substantially equivalent to the predicate device, and that the new device does not raise any questions regarding its safety and effectiveness when compared to the predicate device.

The M1 Capnography Mask has the same intended use, technological characteristics, and is made from the same materials as the Capnoxygen® Mask predicate device. The subject device also shares similar indications for use; device operation, overall technical features and functional capabilities with the predicate device.

The M1 Capnography Mask, as designed, manufactured and tested in a non-clinical setting by Monitor Mask and when compared to the predicate device manufactured by Medsys (Southmedic) previously cleared under K971229, demonstrates that the subject device is as safe, as effective, and performs at least as safely and effectively as the predicate device that is the subject of this 510(k) submission, and therefore is determined to be substantially equivalent to it.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 31, 2013

Monitor Mask, Incorporated
C/O Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K133806
Trade/Device Name: M1 Capnography Mask
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK, BYG
Dated: December 12, 2013
Received: December 16, 2013

Dear Mr. Job:

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.

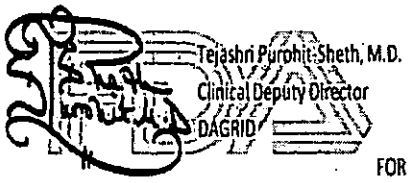
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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. 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,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K133806

Indications for Use Statement

510(k) Number (if known): Not Assigned

Device Name: M1 Capnography Mask

Indications for Use: The M1 Capnography Mask is a single-use device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients. Standard oxygen tubing and two female luer ports for gas sample line attachment are included.

Prescription Use	AND/OR	Over-The-Counter Use
X		
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

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Nayan J. Patel -S
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