K132729

JAN - 9 2014

510(k) SUMMARY

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-433-8050
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Contact Person

Angela Bouse
Senior Regulatory Affairs Specialist

Date Prepared

December 11, 2013

Device Name

Trade Name:	ISO-Gard® Mask
Classification Name:	Apparatus, gas-scavenging
Product Code:	CBN
Regulation Number:	868.5430
Classification:	II
Classification Panel:	Anesthesiology

Predicate Device

This submission demonstrates substantial equivalence to the predicate device ISO-GARD ClearAir Mask - K123176

Device Description

The ISO-Gard Mask system is an oxygen delivery mask that actively scavenges waste anesthetic gases (WAGS) exhaled by patients recovering from surgery in the Post-Anesthetic Care Unit (PACU). Vacuum/suction for scavenging of WAGS is provided by the institution's regulated vacuum source. The proposed device allows for the delivery of supplemental / therapeutic oxygen to patients to aid in their recovery while reducing the amount of patient expelled waste anesthetic agents released to the work environment of the healthcare workers. The mask can be used with or without suction / vacuum to function as a standard oxygen mask with an ETCO2 monitoring port.

Indications for Use

The ISO-Gard® Mask is intended to be used to scavenge waste anesthetic gases from patients during recovery from general anesthesia and to provide supplemental oxygen.

The ISO-Gard® Mask helps to reduce the amount of anesthetic agents released to the work environment of the healthcare worker.

Patient Population

Patients recovering from general anesthesia in the PACU.

Environments of use

The environment of use is – Post-operative Care Units (PACU) in hospital, sub-acute facilities.

Contraindications

None

Substantial Equivalence

The proposed device is substantially equivalent to the predicate devices:

Comparative Characteristics	Predicate K123176 ISO-GARD® ClearAir™ Mask	Proposed ISO-Gard® Mask
Classification Name	Apparatus, gas scavenging	Same
Product Code / CFR	CBN 868.5430 **Secondary** CCK – Gaseous-Phase Carbon Dioxide Gas Analyzer 868.1400	Same
Indications for Use	The ISO-GARD® ClearAir™ Mask is intended to be used to scavenge waste anesthetic gases from patients during recovery from general anesthesia and to provide supplemental oxygen. The ISO-GARD® ClearAir™ Mask helps to reduce the amount of anesthetic agents released to the work environment of the healthcare worker.	Same
Trade Name	ISO-GARD® ClearAir™ Mask	ISO-Gard® Mask
Environment of Use	Hospital, sub-acute facilities PACU	Same
Patient Population	Patients recovering from general anesthesia	Same

	and may need supplemental oxygen Adults	
Contraindications	None	Same
Basic Components	Mask Oxygen delivery tubing Vacuum (scavenging) tubing Mask Manifold controlling oxygen delivery and scavenging	Same
Design, Features, and Specifications		
Mask	Flexible oxygen mask with sealing foam	Same
Method to hold mask on patient for seal	Elastic band / strap	Same
Tubing to deliver oxygen	Standard oxygen tubing	Same
Connects to ETCO2 monitor	Yes	Same
Connector to sampling line	Standard female luer lock	Same
Method of separating gas flows	Divided manifold for separating vacuum and oxygen delivery and then a separate sampling port	Same
Safety features		
Excess negative pressure	Contains entrainment valves if the negative pressure from vacuum is too great Valves are one-way flapper/diaphragm valves that open with minimal negative pressure or flow	Same
Excess positive pressure	Contains entrainment valves if patient's inhalation is greater than the supply of the oxygen	Same
Method to assist in sealing	Foam pad around bridge of nose to assist in sealing of the mask	Same
Method to separate oxygen delivery from scavenging	Mask manifold body is a divided adapter which has an oxygen inlet and a scavenging outlet	Same
Oxygen source	Wall oxygen	Same
Vacuum source	Wall vacuum	Same
Port for sampling end tidal CO2	Port connector on exhalation side of Mask Manifold adapter	Same
Typical oxygen delivered flow rates	Up to 10 lpm	Same
Oxygen at various Oxygen flow rates and Vacuum setting	Delivered oxygen equal or greater than oxygen concentration mask	Same

Mask sizes	Adult	Same
Performance Standards	None	Same
Shelf Life	No shelf life	1 year shelf life
Patient Contacting Materials		
Mask	PVC	Same
Star-Lumen Oxygen Tube	PVC	Same
Connector, Star-Lumen Oxygen Tube	PVC	Same
Gasketing Foam w/Adhesive	Natural ester foam with acrylic pressure sensitive adhesive	Same
Tethered Cap	Thermoplastic Elastomer	Same
One-way inhalation valves	Polyisoprene	Same
One-way Valve Body	Polystyrene, Trans Blue	Same
Oxygen Delivery Port Adaptor	Polypropylene	Same
White Elastic Strap	White Polyester/ Polyisoprene	Same
Mask Manifold	Polystyrene	Same
Suction/Exhalation Port	Polystyrene	Same
Oxygen Port Concentrator	PVC	Same

Comparison to Predicate Device
The proposed ISO-Gard Mask is substantially equivalent to the predicate device with respect to indications for use, technology, materials, and construction. The proposed change is to add a one year shelf life to the ISO-Gard Mask labeling.

- **Indications for Use –**
  The indications for use are identical to the predicate.

- **Technology and construction -**
  The proposed device design, drawings, components, accessories, materials, packaging and product configurations remain unchanged. The proposed change is to add a one year shelf life to the ISO-Gard Mask labeling.

- **Environment of use –**
  The environment of use is identical to the predicate.

- **Patient Population -**
  The patient population is identical to the predicate.

- **Materials -**
  All patient contacting materials are identical to the predicate.

- **Performance Testing**

Nonclinical Performance Testing Summary

Test	Test Objective	Acceptance Criteria
Oxygen Delivery	To evaluate the oxygen delivery performance at variable oxygen flow rates and vacuum levels at standard Tidal Volumes of 500 ml without the use of N_2O	The delivered oxygen percentage using the ISO-Gard Mask must be equal to or greater than a standard medium concentration oxygen mask for all vacuum settings
Scavenging	To evaluate the scavenging performance at variable oxygen flow rates and vacuum levels at standard Tidal Volumes of 500 ml with N_2O	N_2O levels must be lower than with a standard medium concentration oxygen mask
$ETCO_2$	To evaluate the $ETCO_2$ performance in simulated conditions	The traces/waveforms during testing must be distinct and generated consistently

Conclusion
The ISO-Gard Mask has the same indications for use, technological characteristics, and constructions as the predicate. Performance test results demonstrate that the proposed device does not raise new questions of safety and effectiveness and because an acceptance criteria has been met, the device can be found substantially equivalent.

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

January 9, 2014

Teleflex Medical, Inc.
Angela Bouse
Senior Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K132729
Trade Name: ISO-Gard® Mask
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-scavenging apparatus
Regulatory Class: Class II
Product Code: CBN
Dated: December 11, 2013
Received: December 12, 2013

Dear Ms. Bouse:

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 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

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: **ISO-Gard® Mask**

Indications for Use:

The ISO-Gard® Mask is intended to be used to scavenge waste anesthetic gases from patients during recovery from general anesthesia and to provide supplemental oxygen.

The ISO-Gard® Mask helps to reduce the amount of anesthetic agents released to the work environment of the healthcare worker.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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