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

October 30, 2014

Teleflex Medical, Inc.
Brian Gall
Regulatory Affairs Specialist
2917 Weck Drive
Research Triangle Park, NC 27709

Re: K142138
Trade/Device Name: ISO-Gard Mask
Regulation Number: 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: August 01, 2014
Received: August 05, 2014

Dear Mr. Gall:

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,

Tejashri Purohit-Sheth, M.D.

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

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142138

Device Name

ISO-Gard® Mask

Indications for Use *(Describe)*

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.

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)*

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
Fax: 919-433-4996

Contact Person

Brian Gall
Regulatory Affairs Specialist

Date Prepared

August 1, 2014

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 - K132729

Device Description

The ISO-Gard Mask system is an oxygen delivery mask that actively scavenges waste anesthetic gases (WAG) exhaled by patients recovering from surgery in the Post-Anesthetic Care Unit (PACU). Vacuum/suction for scavenging of WAG 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 K132729 ISO-GARD® 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® Mask	Same
Environment of Use	Hospital, sub-acute facilities PACU	Same
Patient Population	Patients recovering from general anesthesia and may need supplemental oxygen	Same

	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	1 year shelf-life	Same
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,HOSE END GRADE,VM 1760 CLEAR 0001 Dye: 07001-57	PVC: Same Dye: CV5M664907 Dark Blue

Comparison to Predicate Device
The proposed ISO-Gard Mask is substantially equivalent to the predicate device with respect to indications for use, technology, labeling, and construction. The proposed material change to the ISO-Gard Mask does not introduce any new issues of safety and effectiveness.

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

- **Technology and construction -**
  The proposed device design, drawings, components, accessories, shelf-life, packaging, labeling, and product configurations remain unchanged.

- **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 device except as noted above. All materials are in compliance with ISO 10993-1:2009 and FDA Bluebook Memorandum G95-1 according to their nature and duration of contact. Testing performed is listed in the performance summary table below.

- **Performance Testing -**
  A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in the table below:

Test	Test Objective	Acceptance Criteria
Oxygen Delivery with Vacuum Tubing	To evaluate the oxygen delivery performance at variable oxygen flow rates and vacuum levels at standard Tidal Volumes of 500 ml	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 and oxygen flow rates
Oxygen Delivery with Vacuum Tubing Removed	To evaluate the oxygen delivery performance with vacuum tubing removed at variable oxygen flow rates	The delivered oxygen percentage using the ISO-Gard Mask must be equal to or greater than a standard medium concentration oxygen mask for all oxygen flow rates
Strength of Connection	To validate the Oxygen Flow Concentrator to Mask bond strength	The Oxygen Flow Concentrator will not detach at 30 lpm flow rate and the initial gauge pressure reading will remain the same as the final pressure reading for each tested mask
Biocompatibility Testing • Cytotoxicity per ISO 10993-5 • Sensitization per ISO 10993-10	To verify biocompatibility of the new material. Testing was performed based on skin/external communication contact of limited duration (< 24 hours)	Must meet the requirements as outlined in ISO 10993-1

• Irritation per ISO 10993-10 • Acute Systemic Toxicity per 10993-11		

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 all acceptance criteria has been met, the device can be found substantially equivalent.