K123176

510(k) Summary

FEB 14 2013

Date prepared: 29-Oct-12

Sponsor:

Teleflex Medical, Inc.
2917 Weck Drive
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Official Contact:

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Proprietary or Trade Name: ISO- GARD® ClearAir™ mask

Common/Usual Name: Apparatus, gas-scavenging

Classification:
Product code – CBN
CFR 868.5430 – apparatus, gas-scavenging
Class 2

Predicate Devices:
K953269 – Advanced Warming Systems (Apotheus) SafeCircuit Manifold
K950771 – Advanced Warming Systems (Apotheus) Adhesive Face Mask
K961150 – Teleflex Bi-Flo $ETCO_2$ nasal cannula

Device Description:
The ISO-GARD® ClearAir™ 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 $ETCO_2$ monitoring port.

The ISO-GARD® ClearAir™ mask is offered in several configurations, the differences being some of the components. **Table 1** lists the configurations.

Technology / Mode of Operation:
The ISO-GARD® ClearAir™ mask is a simple modified oxygen mask which is placed on the patient's face and connected to a standard oxygen source to deliver supplemental oxygen as needed and a separate hose which is connected to a vacuum / suction source to scavenge the patient's exhaled air. The user may adjust the oxygen flow rate and the vacuum rate as needed to deliver the required oxygen and effectively scavenge the WAGS.

Table 1: ISO-GARD® ClearAir™ Mask Product Codes

Product Code	Product Description
8011	ISO-GARD ClearAir Mask, with Tubing
8012	ISO-GARD ClearAir Mask, 8011 with Filter
8013	ISO-GARD ClearAir Mask, Wye and Clamps
8014	ISO-GARD ClearAir Mask, 8013 with Filter

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.

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.

Predicate Device Comparison:
The ISO-GARD® ClearAir™ mask is viewed as substantially equivalent to the predicate devices because:

Indications –

Scavenging waste anesthetic gases and providing supplemental oxygen
The intended uses are identical and the indications for use of scavenging of waste anesthetic gases from patients recovery from general anesthesia and provide supplement oxygen are identical to the predicate, Advanced Warming Systems (Apotheus) SafeCircuit (K953269) when used with the Advanced Warming Systems (Apotheus) Adhesive face mask (K950771).

Discussion –
There are no differences in the intended use and indications for use for the ISO-GARD® ClearAir™ mask and the predicate, Advanced Warming Systems (Apotheus) SafeCircuit (K953269) when used with the Advanced Warming Systems (Apotheus) Adhesive face mask (K950771).

Measuring end-tidal CO_2
The indications for use of measuring end-tidal CO_2 near the patient's mouth are identical to the predicate Hudson (Teleflex) Bi-Flo $ETCO_2$ Nasal Cannula (K961150).

Discussion –
There are no differences in the indications for use for the ISO-GARD® ClearAir™ mask and the predicate, Hudson (Teleflex) Bi-Flo $ETCO_2$ Nasal Cannula (K961150) for delivering supplemental oxygen and gas sampling.

Technology –
The use of a face mask which provides a seal to improve gas scavenging while delivering supplemental oxygen and providing a gas sampling port is identical to the predicates, Advanced Warming Systems (Apotheus) SafeCircuit (K953269) when used with the Advanced Warming Systems (Apotheus) Adhesive face mask (K950771) and Hudson (Teleflex) Bi-Flo $ETCO_2$ Nasal Cannula (K961150).

Providing excess positive and negative pressure relief for safety is equivalent to the predicate Advanced Warming Systems (Apotheus) SafeCircuit (K953269).

The source of oxygen and vacuum are identical to the predicate Advanced Warming Systems (Apotheus) SafeCircuit (K953269).

Discussion –
All the technological characteristics of the proposed device are substantially equivalent to the predicates Advanced Warming Systems (Apotheus) SafeCircuit (K953269) when used with the Advanced Warming Systems (Apotheus) Adhesive face mask (K950771) and Hudson (Teleflex) Bi-Flo $ETCO_2$ Nasal Cannula (K961150) and any difference do not raise any new safety concerns.

Materials –
The materials are either identical to the identified predicates or have been tested per ISO 10993.

Discussion –
The materials have been determined to be safe for the intended use based upon being identical to existing devices or having been tested per ISO 10993.

Environment of Use –
The proposed environment of use in the Post-Operative Care Unit ("PACU") is identical to the predicate, Advanced Warming Systems (Apotheus) SafeCircuit (K953269).

Discussion –
There are no differences in the environments of use for the ISO-GARD® ClearAir™ mask and the predicate, Advanced Warming Systems (Apotheus) SafeCircuit (K953269).

Patient Population –
Patients recovering from general anesthesia and may need supplemental oxygen is identical to the predicate Advanced Warming Systems (Apotheus) SafeCircuit (K953269).

Discussion –
There are no differences in the intended patient population for use for the ISO-GARD® ClearAir™ mask and the predicate, Advanced Warming Systems (Apotheus) SafeCircuit (K953269).

Table 2 is a comparison of the predicates Advanced Warming Systems (Apotheus) SafeCircuit (K953269) and Advanced Warming Systems (Apotheus) Adhesive face mask (K950771), while **Table 3** is a comparison of the proposed device to the predicate Hudson (Teleflex) Bi-Flo $ETCO_2$ Nasal Cannula (K961150).

Table 2 - Predicate Device Comparison - Advanced Warming Systems (Apotheus) SafeCircuit (K953269) and Adhesive Mask (K950771)

Features	Proposed ISO-GARD® ClearAir™ Mask	Predicate K953269 Advanced Warming Systems (Apotheus) SafeCircuit	Predicate K950771 Advanced Warming Systems (Apotheus) Adhesive Mask
Classification name	Apparatus, gas scavenging	Apparatus, gas scavenging	Mask, gas, anesthetic
Product Code / CFR	CBN 868.5430 **Secondary** CCK – Gaseous-Phase Carbon Dioxide Gas Analyzer 868.1400	CBN 868.5430	BSJ 868.5550
Intended Use	To scavenge waste anesthetic gases and provide supplemental oxygen	To scavenge waste anesthetic gases and provide supplemental oxygen	To provide a patient seal when connected to a breathing circuit and allow for gases to be delivered to the patient
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.	To be used to scavenging of wastes anesthetic gases from patients recovery from general anesthesia and provide supplement oxygen When used with the SafeCircuit Adhesive mask and a standard breathing circuit, the unit helps to reduce the amount of anesthetic agents and airborne contaminants released to the work environment of the healthcare worker.	To be used in conjunction with the SafeCircuit (K953269) manifold to provide the seal for scavenging of waste anesthetic gases and delivery of supplemental oxygen

Features	Proposed ISO-GARD® ClearAir™ Mask	Predicate K953269 Advanced Warming Systems (Apotheus) SafeCircuit	Predicate K950771 Advanced Warming Systems (Apotheus) Adhesive Mask
Environment of Use	Hospital, sub-acute facilities PACU	Hospital, sub-acute facilities PACU	Hospital, sub-acute facilities PACU
Patient Population	Patients recovering from general anesthesia and may need supplemental oxygen Adults	Patients recovering from general anesthesia and may need supplemental oxygen Pediatrics and Adults	Used with the SafeCircuit manifold Pediatric and Adults
Basic components	Mask Oxygen delivery tubing Vacuum (scavenging) tubing Mask Manifold controlling oxygen delivery and scavenging	Used with Adhesive mask Breathing circuit for oxygen delivery Connects to vacuum for scavenging Manifold with directional valves for controlling oxygen delivery and scavenging	Adhesive mask used with SafeCircuit manifold
Design, Features, and Specifications			
Mask	Flexible oxygen mask with sealing foam	Uses Adhesive mask to seal around the patient's face	Adhesive mask used with SafeCircuit manifold with an adhesive seal
Method to hold mask on patient for seal	Elastic band / strap	Head strap plus adhesive seal of mask	Head strap plus adhesive seal of mask
Tubing to deliver oxygen	Standard oxygen tubing	Breathing circuit tubing 22 mm	Standard oxygen tubing
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.	Incorporates excess negative pressure relief valves in case of excess vacuum	N/A
Excess positive pressure	Contains entrainment valves if patient's inhalation is greater than the supply of the oxygen	Incorporates excess positive pressure relief valves if patient inhalation exceeds the available supply of gas	N/A

Features	Proposed ISO-GARD® ClearAir™ Mask	Predicate K953269 Advanced Warming Systems (Apotheus) SafeCircuit	Predicate K950771 Advanced Warming Systems (Apotheus) Adhesive Mask
Method to assist in sealing	Foam pad around bridge of nose to assist in sealing of the mask	Adhesive along the edges of the mask to permit a tight seal between the patient's face and the mask	N/A
Method to separate oxygen delivery from scavenging	Mask manifold body is a divided adapter which has an oxygen inlet and a scavenging outlet	Directional valves in the SafeCircuit manifold direct oxygen to the patient which a scavenging from the manifold	N/A
Oxygen source	Wall oxygen	Wall oxygen	Wall oxygen
Vacuum source	Wall vacuum	Wall vacuum	N/A
Port for sampling end-tidal CO_2	Port connector on exhalation side of Mask Manifold adapter	Not offered at the time	See BiFlo nasal cannula (K961150)
Typical oxygen delivered flow rates	Up to 10 lpm	Not specified by could be up to 10 lpm	Up to 10 lpm
Specifications % delivered oxygen at various Oxygen flow rates and Vacuum rate	4 lpm O_2 @ 30 mm Hg = 23% O_2 10 lpm O_2 @ 30 mm Hg = 44% O_2 4 lpm O_2 @ 50 mm Hg = 22% O_2 10 lpm O_2 @ 50 mm Hg = 43% O_2	Not specified but equivalent	N/A
Sizes	1	3	3
Materials	Materials are identical to already cleared devices or have been tested per ISO 10993	Biocompatible materials	Biocompatible materials
Performance Standards	None	None	None

Table 3 - Predicate Device Comparison Table – Teleflex Bi-Flo $ETCO_2$ Nasal cannula (K961150)

Features	Proposed ISO-GARD® ClearAir™ Mask	Predicate K961150 Teleflex Bi-Flo $ETCO_2$ Nasal Cannula
Classification name	Apparatus, gas scavenging	Gaseous-Phase Carbon Dioxide Gas Analyzer
Product Code / CFR	CBN 868.5430 **Secondary** CCK – Gaseous-Phase Carbon Dioxide Gas Analyzer 868.1400	 CCK – Gaseous-Phase Carbon Dioxide Gas Analyzer 868.1400
Intended Use	To scavenge waste anesthetic gases and provide supplemental oxygen and be able to sample for ET CO_2	To provide supplemental oxygen and be able to sample for ET CO_2
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. [To provide supplemental oxygen and be able to sample for ET CO_2] The ISO-GARD® ClearAir™ Mask helps to reduce the amount of anesthetic agents released to the work environment of the healthcare worker.	The Hudson RCI Gas Sampling Oxygen Nasal Cannula is an adjunct to oxygen therapy with its primary function being that of delivering low flow oxygen to a patient while providing a means to sample expired gas. It is intended for use in patients requiring oxygen therapy to improve blood oxygen levels while monitoring expired gas to determine ventilator rate.
Environment of Use	Hospital, sub-acute facilities PACU	Hospital, sub-acute facilities no limitation of specific locations of use
Patient Population	Patients recovering from general anesthesia and may need supplemental oxygen Adults	Patient requiring supplemental oxygen and the ability to sample for ET CO_2 Pediatrics and Adults
Design, Features and Specifications		
Connects to $ETCO_2$ monitor	Yes	Yes
Connector to sampling line	Standard female luer lock	Standard female luer lock
Method of separating gas flows	Divided manifold for separating vacuum and oxygen delivery and then a separate sampling port	Divided cannula for oxygen and gas sampling
Performance standard	None	None
Materials	ISO 10993 tested or identical to predicates	Biocompatible materials

Non-clinical Performance Testing Summary:

Materials – Biocompatibility:
The materials were tested per ISO 10993 – cytotoxicity, sensitization, and irritation as surface contact, skin, limited duration or external communicating, tissue contact, limited duration.

Discussion –
The biocompatibility testing demonstrated that the materials meet the requirements of ISO 10993.

Performance Testing:
A simulation bench set-up was developed and validated to perform design and final product validation testing. The simulated bench testing is designed to evaluate measure and confirm the design performance of the ISO-GARD® ClearAir™ mask.

Pass / Fail criteria:
There is no pass / fail criteria for the ISO-GARD® ClearAir™ mask. The testing performed is for disclosure only.

The tests performed are summarized in **Table 4** below.

Table 4 – Validation / Performance Testing Summary

General Description
Scavenging and Oxygen Delivery performance at variable oxygen flow rates and Vacuum levels at standard Tidal Volumes of 500 ml
Scavenging and Oxygen Delivery performance at variable oxygen flow rates and Vacuum levels at Tidal Volumes outside 500 ml
Intentional leak - Scavenging and Oxygen Delivery performance at variable oxygen flow rates and Vacuum levels at standard Tidal Volumes of 500 ml
Performance when the vacuum source is a suction canister vs. wall vacuum
Performance of oxygen delivery without the use of N_2O
Evaluate simulation set-up to see the build-up of WAGS when no vacuum is applied
Characterize the oxygen delivery performance of medium concentration oxygen masks without N_2O present
ET CO_2 performance in simulated conditions
Comparative ET CO_2 performance of the predicate nasal cannula

Summary of Non-clinical Test Results

Table 5 – Delivered Oxygen % at various O_2 Flow and Vacuum rates (Tidal Volume of 500 ml) - Part 1

	Vacuum		
Oxygen Flow rate	**30 mm Hg**	**40 mm Hg**	**50 mm Hg**
4 lpm	23%	21%	22%
6 lpm	32%	31%	31%
8 lpm	38%	38%	38%
10 lpm	44%	44%	43%

Discussion:
The delivered oxygen % for the ISO-GARD® ClearAir™ mask was equal to or greater than a standard medium concentration oxygen mask for all vacuum settings, see **Table 7**.

Therefore the proposed device can deliver oxygen % equivalent to other oxygen mask while scavenging.

There was no measurable N_2O detected in the chamber, supporting effective scavenging at the patient.

Table 6 – Delivered Oxygen % with no N_2O - Part 5

	Vacuum		
Oxygen Flow rate	**30 mm Hg**	**40 mm Hg**	**50 mm Hg**
4 lpm	34%	27%	28%
6 lpm	37%	31%	30%
8 lpm	37%	35%	33%
10 lpm	40%	36%	35%

Discussion:
The delivered oxygen % for the ISO-GARD® ClearAir™ mask without N_2O was greater than a standard oxygen mask at all flow rates and vacuum, see **Table 8**.

Table 7 – Standard Oxygen Mask Delivered Oxygen % with N_2O - Part 6

Oxygen Flow rate	% Delivered Oxygen
4 lpm	5%
6 lpm	7%
8 lpm	11%
10 lpm	17%

Discussion:
The delivered oxygen % for the standard oxygen mask at all flow rates can be compared with **Table 8** while N_2O built up in the test chamber.

Table 8 – Delivered Oxygen % with no N2O with Standard Oxygen Mask - Part 7

Oxygen Flow rate	Delivered Oxygen %
4 lpm	25%
6 lpm	26%
8 lpm	29%
10 lpm	32%

Discussion:
The delivered oxygen % for the standard oxygen mask at all flow rates without N_2O is less than the performance of the ISO-GARD® ClearAir™ mask under the same conditions, see **Table 5**.

End-tidal CO_2 tracing and waveform with ISO-GARD™ ClearAir™ mask - Part 8

Discussion:
The tracings and waveform were more consistent that compared to the predicate Bi-Flo nasal sampling cannula.

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design features, and non-clinical testing that the proposed device and predicates have been found to 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

February 14, 2013

Ms. Angela Bouse
Senior Regulatory Affairs Specialist
Teleflex Medical, Incorporated
2917 Weck Drive
PO Box 12600
RESEARCH TRIANGLE PARK NC 27709

Re: K123176
Trade/Device Name: ISO-GARD® ClearAir™ Mask
Regulation Number: 21 CFR 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: January 16, 2013
Received: January 17, 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 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,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123176 (To be assigned)

Device Name: **ISO-GARD® ClearAir™ Mask**

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.

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

Lester W. Schultheis Jr
2013.02.15 15:15:07 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123176