K131339

510(k) Summary

Date Prepared: 20-Nov-2013

Mediplus Ltd.
Unit 7, The Gateway Centre
Coronation Road, Cressex Business Park
High Wycombe, Bucks, HP12 3SU UK

Tel – +44 (0) 1494 551299
Fax – +44 (0) 1494 536333

Official Contact: Tim Ward
Operations Manager

Proprietary or Trade Name: Capnomask

Common/Usual Name: Oxygen mask with gas sampling

Classification Name: analyzer, gas, carbon-dioxide, gaseous phase (accessories)
CCK – CFR 868.1400
Class II

Predicate Devices: K971229 – Capnoxygen LLC, Capnoxygen mask

Device Description:
The proposed Capnomask design is like a standard oxygen mask with a port for connecting a gas sampling line which is then to be connected to a gas monitor to measure exhaled carbon dioxide.

The mask has a connector which incorporates ports for connecting standard oxygen tubing and a luer fitting to connect a standard gas sampling line.

In addition, it has air entrainment holes to supply room air if needed.

It is available in sizes ranging from large to small, similar to the predicate device.

Indications for Use:
The Capnomask is intended to deliver supplemental oxygen to patients and monitor breathing by sampling exhaled carbon dioxide.

Environment of use – hospital and sub-acute settings.

Patient population – Non-intubated patients who are breathing spontaneously.

Comparison to Predicates

Attribute	Predicate Capnoxygen LLC Capnoxygen Mask K971229	Proposed Capnomask
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 Capnomask is intended to deliver supplemental oxygen to patients and monitor breathing by sampling exhaled carbon dioxide.
Environments of use	Hospitals and sub-acute setting	Hospitals and sub-acute setting
Prescriptive	Yes	Yes
Patient population	Non-intubated patients who are breathing spontaneously	Non-intubated patients who are breathing spontaneously
Single patient use, disposable	Yes	Yes
Basic components	Face mask Elastic head strap Connector for oxygen tubing and gas sampling line Entrainment ports	Face mask Elastic head strap Connector for oxygen tubing and gas sampling line Entrainment ports
Sizes	Large and Small	Large and Small
Overall dimensions	**Large –** Length – 140 mm Width – 89 mm (at widest point) Height – 67 mm **Small –** Length - 95 mm Width – 76 mm (at widest point) Height – 59 mm	**Large –** Length – 121 mm Width – 85 mm (at widest point) Height – 72 mm **Small –** Length - 94 mm Width – 74 mm (at widest point) Height – 59 mm
Internal Volume	Large – 155 cc Small – 65 cc	Large – 160 cc Small – 72 cc
Entrainment holes	Yes	Yes
Typical Flow Rate Range	< 10 lpm however this is set by the clinician	< 10 lpm however this is set by the clinician
Method of oxygen delivery and Gas sampling	Split connector with barbed oxygen tubing fitting on top of Luer fitting for attaching a gas sampling line. The gas sampling port extends into the mask	Split connector with barbed oxygen tubing fitting on top of Luer fitting for attaching a gas sampling line. The gas sampling port extends into the mask
Method of holding mask on patient	Elastic band	Elastic band
Performance Testing	Comparative End-tidal CO_2 results and waveform at various settings of oxygen flow rate, tidal volume and breathes per minute	Comparative End-tidal CO_2 results and waveform at various settings of oxygen flow rate, tidal volume and breathes per minute Environmental and Mechanical testing Real-time aging Internal Volume Total VOC

Substantial Equivalence Discussion

The above table compares the key features of the proposed Capnomask with the identified predicate and how the proposed device can be found to be substantially equivalent.

In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K971229 – Capnoxygen LLC Capnoxygen mask.
Discussion – Each device is indicated for use delivering supplemental oxygen and sampling expired gases.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate – K971229 – Capnoxygen LLC Capnoxygen mask. This has been confirmed by dimensional verification, internal volume, entrainment port size, and configuration of the sampling connector.
Discussion – The design incorporates a standard face mask shape, connector for oxygen tubing and luer fitting for connecting a gas sampling line. The minor diffreences in dimenrsions and internal volume are not clinical significant as this mask does not provide an air tight seal and air will leak around the surface as well as through the entrainment holes.

Environment of Use –
The environments of use are identical to predicate - K971229 – Capnoxygen LLC Capnoxygen mask.
Discussion – The environments of use are identical to the predicate K971229 – Capnoxygen LLC Capnoxygen mask.

Patient Population –
The patient population is Non-intubated patients who are breathing spontaneously which is identical to the predicate - K971229 – Capnoxygen LLC Capnoxygen mask.
Discussion – The patient populations are identical to the predicate K971229 – Capnoxygen LLC Capnoxygen mask.

Non-Clinical Testing Summary –
We have performed a number of performance tests which include:

- Comparative CO_2 sampling and waveform performance at various breathing rates, tidal volumes and oxygen flow rates. The testing was performed at oxygen flow rates of 1 lpm, 5 lpm, and 10 lpm and CO_2% of 1% and 5%.
- Real-time aging was performed and the device evaluated for performance to specifications which included pressure drop and resistance.
- Environmental and mechanical testing
- Total VOC

All testing demonstrated that the proposed device is substantially equivalent to the predicate device. It was noted that with higher oxygen flow rates and breath rates that the measured EtCO2 would be diluted which is as expected. As the proposed devices are a tool to detect the qualitative presence of breathing and delivery supplemental oxygen.

Materials –
We have performed ISO 10993 testing on the component materials of the Capnomask which has parts which are considered as Surface (direct) contact and Externally Communicating (Indirect) mucosal contact with the patient which means the following tests are required if a material certification cannot be provided.

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Total VOC

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate 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

November 25, 2013

Mediplus, Limited
C/O Mr. Paul Dryden
President, Regulatory Consultant
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K131339
Trade/Device Name: Capnomask
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: II
Product Code: CCK
Dated: October 21, 2013
Received: October 24, 2013

Dear Mr. Dryden:

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,

Erin Keith

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: K131339

Indications for Use:

The Capnomask is intended to deliver supplemental oxygen to patients and monitor breathing by sampling exhaled carbon dioxide.

Environment of use – hospital and sub-acute settings.

Patient population – Non-intubated patients who are breathing spontaneously.

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)

Nayan J. Patel -S
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