MAR 2 8 2014

K133540

510(k) Summary

27-Mar-14

Maxtec, LLC
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Salt lake City, UT 84107

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Official Contact: Tammy Lavery, Regulatory Affairs & Quality

Proprietary or Trade Name: FLOCAP

Common/Usual Name: CO_2 detector

Classification Name: Carbon dioxide gas analyzer
CCK – 21 CFR 868.1400
Class 2

Predicate Devices: Mercury Medical – StatCO_2 – K021576

Device Description

The proposed FLOCAP is comprised of several components:

- Housing with standard 15 mm / 22 mm fittings to connect to ventilatory assist devices and a face mask or endotracheal tube
- Colorimetric litmus media which has been treated with chemical to detect the presence of CO_2 by a change in pH
- A spinner / vane which spins when there is expiratory flow. It is to detect presence of expiratory flow

Indications for Use

The FLOCAP is to provide a semi-quantitative visualization of the CO_2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.

The FLOCAP has a visual indicator to visually detect the end of exhalation.

For use up to 24 hours.

For patients greater than 15 kg (33 lbs.)

Environment of use – hospital, sub-acute, pre-hospital, transport

Predicate Device Comparison:

The Maxtec FLOCAP CO_2 detector is viewed as substantially equivalent to the predicate device based upon the following:

Indications –

Indicated to provide semi-quantitative visualization of the CO_2 in the patient airway and as an adjunct in patient assessment for use in hospital, sub-acute and pre-hospital, and

- transport for patient greater than 15 kg and up to 24 hours of use are identical to the predicate.

Discussion – The indications for use are identical for the proposed and predicate device, Mercury Medical STAT CO_2 – K021576.

Contraindications –

- The contraindications are almost identical to the predicate.

Discussion – We added hypercarbia as part of the contraindications, but this does not alter the contraindications and they can be found to be substantially equivalent to the predicate - Mercury Medical STAT CO_2 – K021576.

Technology –

- The technology of a colorimetric, pH sensitive, media to detect the presence and the amount of CO_2 is identical to the predicate.

Discussion - There are no differences in technology between the proposed device and the predicate - Mercury Medical STAT CO_2 – K021576.

Environment of Use –

- Hospital, sub-acute, Pre-hospital, and transport environments of use are identical to the predicate.

Discussion - The environments of use are similar between the proposed device and the predicates – Mercury Medical STAT CO_2 – K021576. While the predicate only specifies hospital and transport, sub-acute is a subset of hospitals and pre-hospital is a subset of transport (EMS). The proposed language is only to clarify the environments of use better.

Non-clinical Performance Testing

- We compared performance to specifications to the predicate as well as performed specific tests related to the device. These tests included:
  - Color change response time
  - Leakage
  - Minimum static flow indication
  - Anti-fog
  - Packaging integrity per ISTA 2A
  - Operational environment
  - Shelf-life (aging)
  - Drop test
  - Duration of Use
  - Burst Pressure
  - Compliance per ISO 9360-1
  - Pressure Drop per ISO 9360-1
  - Internal Volume (Dead space)
  - Usability per BS EN 62366

Discussion - The bench testing as well as the comparative specifications we found to be similar to the predicate – Mercury Medical STAT CO_2 – K021576

Materials –

- The materials utilized in the FLOCAP are typical and common and have been evaluated per ISO 10993-1 for biocompatibility

Discussion – The materials were tested in the final, finished form and found to pass ISO 10993-1 testing for cytotoxicity, sensitization, and Intracutaneous reactivity.

Features	Predicate Mercury Medical STAT CO_2 (K021576)	Proposed FLOCAP
Indications for use	The Mercury STAT CO_2 is intended to provide a semi-quantitative visualization of the CO_2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.	The FLOCAP is to provide a semi-quantitative visualization of the CO_2 in the patient airway. It is an adjunct in patient assessment, to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. The FLOCAP has a visual indicator to visually detect the end of exhalation.
Patient Use / Duration if use	Single patient use, disposable, < 24 hours	Single patient use, disposable, < 24 hours
Environment of Use	Hospital Transport	Hospital Sub-acute Pre-hospital Transport
Patient Population	Greater than 15 kg (33 lbs.)	Greater than 15 kg (33 lbs.)
Contraindications	• Do not use to detect hypercapnia • Do not use to detect main stem bronchial intubation • Do not use during mouth-to-tube ventilation • Do not use to detect oropharyngeal tube placement When low pulmonary perfusion coincides with accidental esophageal intubation, colorimetric CO_2 indication cannot be properly interpreted. However, if proper tube placement is ascertained by independent means, then the STAT CO2 may be used to help assess the progress of positive pressure ventilation as evidenced by an increase in end-tidal CO_2.	• Do not use to detect hypercapnia / hypercarbia • Do not use to detect main stem bronchial intubation • Do not use during mouth-to-tube ventilation • Do not use to detect oropharyngeal tube placement When low pulmonary perfusion coincides with accidental esophageal intubation, colorimetric CO_2 indication cannot be properly interpreted. However, if proper tube placement is ascertained by independent means, then the FLOCAP may be used to help assess the progress of positive pressure ventilation as evidenced by an increase in end-tidal CO_2.

Features	Predicate Mercury Medical STAT CO_2 (K021576)	Proposed FLOCAP
Principle of Operation	Colorimetric, pH sensitive dye for detecting presence of CO_2 and the amount	Colorimetric, pH sensitive dye for detecting presence of CO_2 and the amount
Placement	Between manual resuscitator or pressure source and the patient face mask or endotracheal tube	Between manual resuscitator or pressure source and the patient face mask or endotracheal tube
Features, Specifications and Performance		
Standard 15 / 22 mm connections Per ISO 5356-1	Yes	Yes
Internal Volume (dead space)	25 ml	25 ml
Weight	22 gr	23 gr
Compliance per ISO 9360-1	Not provided	0.44 ml/kPa
Leakage per ISO 9360-1	Not provided	0.0 ml/min
Pressure Drop per ISO 9360-1	@ 60 lpm – 3.0 cm H_2O	@ 30 lpm – 0.7 cm H_2O @ 60 lpm – 2.7 cm H_2O @ 90 lpm – 5.7 cm H_2O
Shelf-life	2 years	2 years
Packaging and method to "activate"	Polybag Remove plastic tab to expose litmus media	Foil pouch Nothing required to be done to activate
Detected % CO_2 ranges and Colors	0% CO_2 – Blue 1.0 to 2.0% CO_2 – Green > 5.0% CO_2 – Permanent Yellow	0% CO_2 – Purple 1.0 to 2.0% CO_2 – Beige > 5.0% CO_2 – Yellow
Method of Communicating Meaning of Color Changes	Matching Colored Label on the Outside of the device	Matching Colored Label on the Outside of the device
Meanings of detecting patient exhalation	Color change	Color change Spinning vane – visual indicator (detects exhalation flow > 1 lpm)
Standards	ISO 5356-1 – Conical fittings	ISO 5356-1 – Conical fittings ISO 9360-1 HME in part

Differences –

There are limited differences between the proposed FLOCAP and the predicate.

- Filter element
  - The predicate includes a filter element to capture any gross particulates that may come from the device or to protect the colorimetric media from an patient secretions
  - The proposed device does not contain a filter element, as some predicate colorimetric CO_2 detectors. For the FLOCAP gas passes around the media and does not have to go through it so protection from patient secretions is less of an issue.

Discussion – All these devices contain notes that if the device is subjected to patient secretions it should be removed and replaced. Therefore this difference is not significant and does not raise any new concerns of safety or effectiveness.

- Pull tab to active the device
  - The predicate has a tab which seals the media from any ambient air and must be removed prior to use.
  - The proposed FLOCAP does not require this tab as the media as the packaging has demonstrated that it can be safely stored for 2 years without deterioration in performance.

Discussion – The proposed FLOCAP without the pull tab does not raise any new concerns.

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 be 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

April 9, 2014

Maxtec, Limited Liability Company
Mr. Paul Dryden
Consultant
6526 South Cottonwood Street
Salt Lake City, UT 84107

Re: K133540
Trade/Device Name: FLOCAP
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: February 21, 2014
Received: February 24, 2014

Dear Mr. Dryden:

This letter corrects our substantially equivalent letter of March 28, 2014.

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,

Todd D. Courtney -S
2014.04.09 14:38:11 -04'00'

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

Indications for Use Statement

510(k) Number: K133540 (To be assigned)

Device Name: FLOCAP

Indications for Use:

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Environment of use – hospital, sub-acute, pre-hospital, transport

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)

Todd D. Courtney -S
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