May 23, 2019

Maxtec, LLC
Paul Dryden
Consultant
2305 S 1070 W
Salt Lake City, Utah 84119

Re: K182362
Trade/Device Name: MaxCap Ped and MaxCap Neo
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: April 19, 2019
Received: April 22, 2019

Dear Paul 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement on last page.

510(k) Number *(if known)*

K182362

Device Name

MaxCap Neo and MaxCap Ped

Indications for Use *(Describe)*

The Maxtec MaxCap Neo and MaxCap Ped are indicated 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.

Patient Population:
MaxCap Neo is intended for use with neonates and infants 250g to 6kg.
MaxCap Ped is intended for use with pediatric patients 1kg to 15kg

Environment of Use:
Hospital, sub-acute, pre-hospital, transport.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

23-May-19

Maxtec, LLC
2305 South 1070 West
Salt lake City, UT 84119

Tel: (385) 549-8080
Fax: (801) 973-6090

Official Contact: Tammy Lavery, Regulatory Affairs & Quality

Proprietary or Trade Name: MaxCap Neo and MaxCap Ped

Common/Usual Name: CO_2 detector

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

Predicate Devices: Mercury Medical - Mercury Medical Mini Stat CO_2 End Tidal CO_2 - K031411
Mercury Medical - Mercury Medical NeoStatCO_2 <Kg - K083056

Reference device: Maxtec - FloCap CO2 Indicator - K133540

Device Description
The proposed MaxCap Neo and MaxCap Ped are comprised of several components:

- Housing with standard 15 mm / 22 mm fittings to connect to the ventilator assist device 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

Indications for Use
The Maxtec MaxCap Neo and MaxCap Ped are indicated 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.

Patient Population:
MaxCap Neo is intended for use with neonates and infants 250g to 6kg.
MaxCap Ped is intended for use with pediatric patients 1kg to 15kg

Environment of Use:
Hospital, sub-acute, pre-hospital, transport.

Predicate Device Comparison:

The proposed Maxtec MaxCap Neo and MaxCap Ped CO_2 detectors are similar except for their intended patient population. In order to make a substantial equivalence comparison, we have to use 2 predicates which match the proposed patient population.

These predicates are:

- Mercury Medical – Mini-Stat CO_2 – K031411 for pediatrics
- Mercury Medical – Neo-Stat CO_2 – K083056 for neonates.

In addition, since the technological characteristics, construction, materials and CO_2 detection performance is equivalent to the Maxtec FloCap (K133540) we have included it as a reference device.

The Maxtec MaxCap Neo and MaxCap Ped CO_2 detectors are viewed as substantially equivalent to the predicate devices 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 patients between 250g and 6kg (MaxCap Neo) or 1kg and 15kg (MaxCap Ped) and up to 6 hours of use are similar to the predicates.

Discussion – The indications for use are similar for the proposed and predicate devices, Mercury Medical – Mini Stat CO_2 – K031411 and Mercury Medical – Neo-Stat CO_2 – K083056.

Contraindications –

- The contraindications are similar 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 – Mini Stat CO_2 – K031411 and Mercury Medical – Neo-Stat CO_2 – K083056, and reference Maxtec – FLOCAP – K133540.

Technology –

- The technology of a colorimetric, pH sensitive, media to detect the presence and the amount of CO_2 is identical to the reference K133540 and similar to the predicates.

Discussion - There are no differences in technology between the proposed device and the predicates - Mercury Medical – Mini Stat CO_2 – K031411 and Mercury Medical – Neo-Stat CO_2 – K083056, and reference Maxtec – FLOCAP – K133540.

Environment of Use –

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

Discussion - The environments of use are similar between the proposed device and the predicates – Mercury Medical – Mini Stat CO_2 – K031411 and Mercury Medical – Neo-Stat

CO_2 – K083056, and reference Maxtec – FLOCAP – K133540. While the predicate Mercury Medical – Mini Stat CO_2 – K031411 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 use environments.

Non-clinical Performance

We have performed the following performance data and testing for the new models:

- Color change accuracy
- Color change response time
- Drop test
- Duration of Use
- Flow Resistance / Back Pressure
- Internal Volume (Dead space)
- Device weight
- Shelf-life (aging)

Tests applicable to the MaxCap Ped and MaxCapNeo that were performed on the reference Maxtec FloCap K133540 include:

- Packaging integrity per ISTA 2A
  - The packaging for the proposed devices is identical
- Operational environment
  - The operating environment for the proposed devices is identical
- ISO 10993-1 for biocompatibility
  - The materials for the proposed devices are identical, except they do not include the anti-fog coating

Therefore, the reference FloCap (K133540) can be used to represent the proposed models.

Biocompatibility of Patient Contacting Materials –

- The materials utilized in the MaxCap Neo and MaxCap Ped are similar to the reference Maxtec FloCap K133540 except the removal of the anti-fog coating.

Discussion – The devices have identical patient contact and the MaxCap has less duration of use, The materials were evaluated in K133540 tested in the final, finished form and found to meet ISO 10993-1 testing for cytotoxicity, sensitization, and Intracutaneous reactivity. In addition, we have performed gas emission VOC and $PM_{2.5}$ testing. We note that the subject devices do not include the anti-fog material. The change in population does not raise different question of safety and effectiveness as less: maximum 6 hours vs. 24 hours.

Performance Testing

- Full performance testing was completed on the Maxtec – FLOCAP – K133540, including testing such as shelf-life, color change response time, leakage, anti-fog, packaging integrity operational environment, usability, duration of use, burst pressure, and biocompatibility were previously performed and cleared in K133540. Much of the testing

is directly applicable to the MaxCap Ped and Neo, since only the form factor has changed.

Certain tests were performed on the reference FloCap (K133540) which were not repeated as the materials, assembly methods and packaging are identical. These tests included:

- Operational environment
    - Only the litmus element is affected by the operational environment, and it is identical in materials and chemistry to the FloCap
- Packaging integrity
    - The packaging is equivalent to FloCap so new testing is not required

Discussion – Through the bench testing as well as the comparative specifications we found the MaxCap Ped and Neo devices to be similar to the predicates.

Features	Proposed MaxCap Neo and MaxCap Ped	Predicate Mercury Neo-Stat CO_2 K083056	Predicate Mercury Mini Stat CO_2 K031411	Reference Maxtec FloCap K133540
Indications for Use	The Maxtec MaxCap Neo and MaxCap Ped are indicated 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 Neo-Stat CO_2 is indicated 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. Intended for use with neonate and infant patients from 250g to 6kg.	The Mercury Medical Mini StatCO_2 End Tidal CO_2 Detector 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 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	Single patient use, disposable	Single patient use, disposable	Single patient use, disposable	Single patient use, disposable
Environment of Use	Hospital, sub-acute facilities, pre-hospital and transport	Hospital, sub-acute facilities, pre-hospital and transport	Hospital, Transport	Hospital, sub-acute facilities, pre-hospital and transport
Patient Population	MaxCap Neo – 250g to 6kg MaxCap Ped – 1kg to 15kg	250g to 6kg	1kg to 15kg	>15 kg

Features	Proposed MaxCap Neo and MaxCap Ped	Predicate Mercury Neo-Stat CO_2 K083056	Predicate Mercury Mini Stat CO_2 K031411	Reference Maxtec FloCap K133540
Contraindications	• Do not use the MaxCap for the detection of Hypercapnia/ Hypercarbia. • Do not use the MaxCap for the detection of main-stem bronchial intubation. • Do not use the MaxCap during mouth to tube ventilation. • Do not use the MaxCap to detect oropharyngeal tube placement. • Standard clinical assessment must be used.	• Do not use for detection of hypercapnia • Do not use for the detection of main-stem bronchial intubation • Do not use during mouth to tube ventilation • Do not use the CO_2 detector to detect oropharyngeal tube placement • Standard clinical assessment must be used	Unknown	• 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
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	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	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
Breathes to effect color change	< 6 breaths	< 6 breaths	< 6 breaths	< 6 breaths
Duration of Use	Up to 6 hours	Up to 24 hours	Up to 24 hours	Up to 24 hours

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Features	Proposed MaxCap Neo MaxCap Ped	Predicate Mercury Neo-Stat CO_2 K083056	Predicate Mercury Mini Stat CO_2 K031411	Reference Maxtec FloCap K133540
Features, Specifications and Performance				
Standard 15 / 22 mm connections	Yes	Yes	Yes	Yes
Internal Volume (dead space)	MaxCap Neo – 1.0 cc MaxCap Ped – 2.4 cc	1cc	3cc	N/A
Weight	< 5 g MaxCap Neo < 4 g MaxCap Ped	3g	5g	N/A
Resistance to Flow (Pressure Drop)	MaxCap Neo 2.1 cmH_2O @ 5 Lpm 5.2 cmH_2O @ 10 Lpm 9.8 cmH_2O @ 15 Lpm MaxCap Ped 0.2 cmH_2O @ 5 Lpm 0.5 cmH_2O @ 10 Lpm 2.8 cmH_2O @ 30 Lpm	3.41 cmH_2O @ 5 Lpm 11.22 cmH_2O @ 10 Lpm 23.77 cmH_2O @ 15 Lpm (As tested)	1.2 cmH_2O @ 10 Lpm+ 2.5 cmH_2O @ 10 Lpm* 8.8 cm H_2O @ 30 Lpm+	N/A
Shelf-life	1 year	2 years	2 years	3 years
Detected % CO_2 ranges and Colors	0% CO_2 – Purple 1.0 to 2.0% CO_2 – Beige > 5.0% CO_2 – Yellow	0% CO_2 – Blue 1.0 to 2.0% CO_2 – Green 2.0 to 5.0% CO_2 – Yellow /Green > 5.0% CO_2 – Permanent Yellow	0% CO_2 – Blue 1.0 to 2.0% CO_2 – Green 2.0 to 5.0% CO_2 – Yellow 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	Matching Colored Label on the Outside of the device	Matching Colored Label on the Outside of the device
Means of detecting patient exhalation	Color change	Color change	Color change	Color change

***** The reported specification in the predicate literature is presented above which is different than that presented in the 510(k) Summaries.

+ These are values from K083506 510(k) Summary.

Differences

The differences in the proposed device and the predicates relate to:

- Small differences in internal volume
- Lower resistance to flow
- Shorter shelf-life
  - Shelf-life is not a clinical concern
- Shorter duration of use
  - These devices are used in emergency situations and typically the duration of use is < 1 hour, so having a 6 hour duration of use is acceptable for the intended use

These differences do not raise different questions of safety and effectiveness compared to the predicates.

S**ubstantial Equivalence Conclusion**

Testing and comparison to the predicates have demonstrated that the proposed devices can be found substantially equivalent and any differences do not raise different issues of safety and effectiveness.