January 17, 2020

Meditera Tibbi Malzeme San. ve Tic. A.S.
℅ Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K192563
Trade/Device Name: Altera Gas Sampling Lines
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: December 18, 2019
Received: December 19, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant 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 below.*

510(k) Number *(if known)*

**K192563**

Device Name

**Altera Gas Sampling Lines**

Indications for Use *(Describe)*

The Altera Gas Sampling Lines are intended to connect from a port in the breathing circuit to the expired gas monitor.

Type of Use *(Select one or both, as applicable)*

**XX** Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K192563

**Date Prepared:** 16-Dec-2019

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**Official Contact:** Cenk Kılıç Kalkan
Quality Assurance Team Leader

**Proprietary or Trade Name:** Altera Gas sampling Lines

**Common/Usual Name:** Carbon Dioxide Gas Analyzer

**Classification:** 21CFR 868.1400
CCK - Carbon Dioxide Gas Analyzer
Class II

**Predicate Device:** K171678 – Vyaire – Vital Signs Gas sampling Lines

**Device Description:**
The Altera Gas Sampling Lines consists of a disposable single patient use coextruded gas sampling line which is provided in 3 different lengths: 2, 2.5, and 3 meters. The disposable single patient use gas sampling lines are smooth narrow diameter tubes that have standardized male luer connectors at both ends.

The gas sampling line connects from a port in a circuit to an expired gas monitor. The gas sampling line provides a conduit for drawing gas samples from the sampling port to the gas monitor to analyze respiratory gases. These disposable single patient use gas sampling lines are used to transmit one directional flow of gas sample from the patient breathing circuit port to the gas module host device. A vacuum source and gas measurement sensors are in the host device, which pull the gas from the sampling port to the host device for gas monitoring.

**Principle of Operation:**
The principle of operation is that gas is pulled from a luer port on a circuit on the patient end of the tubing to the other end which is connected to a gas sampling monitor which has an internal vacuum pump pulling the gas to be sampled.

**Indications for Use:**
The Altera Gas Sampling Lines are intended to connect from a port in the breathing circuit to the expired gas monitor.

The following table presents a comparison of the subject device to the predicate.

| Attribute | Predicate<br>Vyaire Vital Signs | Proposed<br>Altera GSL | Comparison | Does the difference raise new questions of safety and effectiveness? |
|---|---|---|---|---|
| **K#** | K171678 | N/A | N/A | N/A |
| **Classification** | CCK – Carbon Dioxide Gas Analyzer<br>21 CFR 868.1400 | CCK – Carbon Dioxide Gas Analyzer<br>21 CFR 868.1400 | Same | No |
| **Indications for Use** | The Vital Signs Gas Sampling Lines are intended to connect from a port in the breathing circuit to the expired gas monitor. These gas sampling lines are used with GE Healthcare Compact Airway modules and CARESCAPE Respiratory modules for monitoring CO2, O2, N2O and anesthetic agents and with E-miniC for monitoring CO2. | The Altera Gas Sampling Lines are intended to connect from a port in the breathing circuit to the expired gas monitor. | Similar | No.<br>The predicate is specific to certain monitors, but they have the same intended use. |
| **Principle of Operation** | Gas is pulled from one end of the tube to the other by a pump in the gas sampling device. | Gas is pulled from one end of the tube to the other by a pump in the gas sampling device. | Similar | No |
| **Patient Population** | Any patient population requiring gas monitoring | Any patient population requiring gas monitoring | Similar | No |
| **Environments of use** | Hospitals | Hospitals, sub-acute, pre-hospital | Similar | No.<br>Expired gas monitoring is utilized in other clinical settings |
| **Compatibility with environment and other devices** | Designed for the use with GE Healthcare Compact Airway modules and CARESCAPE Respiratory modules for monitoring CO2, O2, N2O and anesthetic agents and with EminiC for monitoring CO2. | Designed for use with gas monitoring device (for example a capnography) with luer connections for gas sampling. | Similar | No.<br>While the predicate lists specific monitors, all expired gas sampling tend to utilize a luer fitting |
| **Single patient use, disposable** | Yes | Yes | Similar | No |

| Attribute | Predicate<br>Vyaire Vital Signs | Proposed<br>Altera GSL | Comparison | Does the difference raise new questions of safety and effectiveness? |
|---|---|---|---|---|
| **Characteristics** | | | | |
| **Materials** | ISO 10993 tested<br>Co-extruded PE/EVA/PVC | ISO 10993 tested<br>Co-extruded PE/EVA/PVC | Similar | No |
| **Performance testing** | Flow resistance –<br>~ 26 $cmH_2O$ @ 150 ml/min<br>Leakage per ISO 80601-2-55<br>< 10 ml/min | Flow resistance –<br>~ 12 - 17.5 $cmH_2O$ @ 150 ml/min<br>Leakage per ISO 80601-2-55<br>< 10 ml/min | Similar | No<br>Flow resistance is just a reported value |
| **Tubing**<br>**ID / OD** | ID - 1.2 mm<br>OD - 2.8 mm | ID - 1.2 mm<br>OD - 2.8 mm | Similar | No |
| **Lengths** | Up to 3 meters | 2, 2.5 and 3 meters | Similar | No |
| **Connectors** | Standard ISO 80369 small bore luer fittings – male / female | Standard ISO 80369 small bore luer fittings – male / female | Similar | No<br>Predicate referenced ISO 594-2 vs. ISO 80369-7 |
| **Separation force of connectors** | >35 Newtons | >35 Newtons | Similar | No |
| **Leakage of connectors** | 0.02-0.05 ml/min | < 0.005Pa*m3/s<br>Units per ISO 80369-7 | Similar | No |
| **ISO 594-2 or**<br>**ISO 80369-7** | ISO 594-2<br>Unscrewing torque<br>Resistance to overriding<br>Stress cracking | ISO 80369-7<br>Unscrewing torque<br>Resistance to overriding<br>Stress cracking | Similar | No<br>Both devices passed the requirements for luer fittings even though they used a different standard |
| **Performance post aging** | N/A | After 3 years accelerated aging performance testing still met the pre-established acceptance criteria | - | No |

**Performance Testing**

We completed the following performance testing:

- Flow resistance
- Accelerated ageing including environmental
- 3 years shelf-life
- Mechanical testing
- Luer fitting per ISO 80369-7:2018
- Fluid leakage
- Air leakage
- Stress cracking
- Separation force
- Unscrewing torque
- Resistance to overriding
- Air leakage (ISO 80601-2-55)

**Discussion of Differences and Substantial Equivalence Conclusion**

There are no differences between the proposed device and the predicate. The performance testing has demonstrated that the subject devise met the applicable standard performance requirements. There were no differences which raise different risks vs. the predicate.

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.