April 30, 2018

Vyaire Medical, Inc.
Colleen O'keefe
Acting Director
26125 N. Riverwoods Blvd.
Mettawa, Illinois 60045

Re: K171678
Trade/Device Name: Vital Signs™ Gas Sampling Lines
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 22, 2018
Received: March 26, 2018

Dear Colleen O'keefe:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171678

Device Name
Vital Signs Gas Sampling Lines

Indications for Use *(Describe)*

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.

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.

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

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510K Summary

1. SUBMITTER

Vyaire Medical
26125 Riverwoods Blvd.
Mettawa, IL 60045
Phone: 224-706-6818

Contact Person: Colleen Watson O'Keeffe
Date Prepared: June 2, 2017

2. Device

Product Name:	Vital Signs™ Gas Sampling Lines
Trade or Proprietary Name:	Vital Signs™
Device Name:	Gas Sampling Line
Common Name:	Gas Sampling Line
Classification Name:	Analyzer, gas, carbon dioxide, gaseous-phase 21 CFR 868.1400
Regulatory Class:	II
Product Code:	CCK

3. Predicate Device

Disposable Gas Sampling Line cleared under K946044 on December 27, 1994. This predicate device has not been subject to a design-related recall.

4. Device Description

Vital Signs Gas Sampling Lines consists of a disposable single patient use coextruded gas sampling line that is compatible with GE Healthcare Compact Airway, E-MiniC and CARESCAPE Respiratory Modules and are provided in four different lengths: 2 meters, 2.5 meters, 3 meters and 6 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 the breathing circuit to an expired gas monitor. The gas sampling line provides a conduit for drawing gas samples from the

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breathing circuit 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 located in the host device, which pull the gas from the breathing circuit port to the host device for gas monitoring. The gas sampling lines are accessories to the gas monitoring devices.

5. Principle of Operation

The gas sampling line provides a conduit for drawing gas samples from the breathing circuit port to the gas monitor. Gas is pulled from one end of the tube to the other by a pump in the gas sampling device. Gas sampling line is connected to gas monitor and suitable breathing circuit component with standardized Luer connector.

6. Indication 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.

7. Comparison of technological characteristics with the predicate device

Element of comparison	Proposed Device Gas Sampling Line	Primary Predicate Device Disposable Gas Sampling Line K946044	Comparison Result	Does the difference raise any questions of safety and effectiveness?
Indications for Use	The 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 gas sampling lines are intended to provide a conduit from the patient port in the breathing circuit to the gas monitor.	Different	While the intended use is the same, the indications differ slightly in that the subject device specifically states which devices they are intended to be used with. This difference does not raise different questions of safety or effectiveness.
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.	Same	N/A
Patient Population	Any patient population requiring gas monitoring	Any patient from which gas monitoring is required during the patients breathing cycle.	Same	N/A

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Element of comparison	Proposed Device Gas Sampling Line	Primary Predicate Device Disposable Gas Sampling Line K946044	Comparison Result	Does the difference raise any questions of safety and effectiveness?
Environment of Use	Hospital Environment	Hospitals	Same	N/A
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 E-miniC for monitoring CO2.	Designed for use with gas monitoring device (for example a capnography) with luer connections for gas sampling.	Similar	No. The only difference is that the proposed gas sampling lines are specifically indicated for use with GE Healthcare Compact Airway modules and CARESCAPE Respiratory modules
Characteristics				
Inner diameter	1.2mm	1.34 mm	Similar	No. The difference in inner diameter is required for compatibility with referenced GE equipment.
Outer diameter	2.8mm	2.95 mm	Similar	No. The difference in outer diameter is required for compatibility with referenced GE equipment.
Separation force	>35 Newtons (PRO-CA-HL-17-005)	>35 Newtons (PRO-CA-HL-17-009)	Same	N/A
Flow resistance	26.22-27.76mbar at 150ml/min with 3 meter gas sampling line (PRO-CA-HL-17-005)	16.61-19.17mbar at 150ml/min with 3 meter gas sampling line (PRO-CA-HL-17-009)	Similar	No. The difference in flow resistance is due to the difference in inner diameter which is required for compatibility with referenced GE equipment.
Leakage	0.02-0.05 ml/min	<1.0ml/min	Same	N/A
Connector	Luer connector according to ISO 594-2 (PRO-CA-HL-17-005)	Luer connector according to ISO 594-2 (PRO-CA-HL-17-009)	Same	N/A

8. Performance Data

The Vital Signs Gas Sampling Lines tested in accordance with the following standards

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8.1 Performance Testing

Performance Characteristics	Standard
Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings	ISO 594-2:1998
Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors	ISO 80601-2-55 First edition 2011-12-15

Test	Relevant Standard	Standard Section	Acceptance Criteria	Result
Gauge test	ISO 594-2 : 1998	4.1	The end of the conical Luer fitting shall lie between the minimum and maximum limit planes of the gauge for all tested samples.	Pass
Separation force	ISO 594-2 : 1998	4.3	For all tested samples Luer connectors shall remain attached to the reference fitting when pulled with 35 N force for minimum of 10 seconds.	Pass
Unscrewing torque	ISO 594-2 : 1998	4.4	For all tested samples Luer connectors shall remain attached to the reference fitting when unscrewed with 0.02Nm for minimum of 10 seconds.	Pass
Ease of assembly	ISO 594-2 : 1998	4.5	For all tested samples a satisfactory fit shall be achieved when connection is assembled applying an axial force not exceeding 20N and while applying a torque not exceeding 0.08Nm.	Pass
Resistance to overriding	ISO 594-2 : 1998	4.6	For all the tested samples the reference connector shall not override the threads of sample Luer connector when applying a torque not less than 0.15Nm for period of 5 seconds.	Pass
Stress cracking	ISO 594-2 : 1998	4.7	For all the tested samples there shall be no evidence of stress cracking in the Luer connectors after keeping the test sample connected to the reference fitting for 48 ±1 hours.	Pass

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Test	Relevant Standard	Standard Section	Acceptance Criteria	Result
Security of attachment (Pull test)	N/A	N/A	35 Newtons	Pass
Leakage test	ISO 80601-2-55:2011	201.102	≤ 10 ml/min	Pass
Flow resistance test	N/A	N/A	21-35 mbar for 3 meter gas sampling line 42-70 mbar for 6 meter gas sampling line	Pass
"GAS SAMPLE" Marking test	ISO 80601-2-55:2011	201.7.2.101	Marking shall be clear and legible as defined by ISO 80601-2-55	Pass

8.2 Biocompatibility

Test for surface contact of mucosal membrane via airway with limited exposure (less than 24 hours): Cytotoxicity, Sensitization, Irritation

Performance Characteristic	Standard
Biological Evaluation of Medical Devices–Part 1: Evaluation and Testing	AAMI/ANSI/ISO 10993-1:2009
Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity	AAMI/ANSI/ISO 10993-5:2009 (R2014)
Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization.	AAMI/ANSI/ISO 10993-10:2010 (R2014)

9. Conclusion

The non-clinical data support the substantial equivalence of the proposed device. Also, test results demonstrate that the device is as safe and effective as the predicate and therefore substantially equivalent to the predicate device.