August 23, 2019

Vyaire Medical
Elmar Niedermeyer
Cnstl. Regulatory Affairs
Leibnizstrasse 7
Hoechberg, 97204 De

Re: K183567
Trade/Device Name: Vyntus/SentrySuite Product Line
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: Class II
Product Code: BZC, DPS
Dated: July 23, 2019
Received: July 25, 2019

Dear Elmar Niedermeyer:

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,

for James J. Lee, PhD
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)*
K183567

Device Name
Vyntus/SentrySuite Product Line

Indications for Use *(Describe)*

The Vyntus/SentrySuite Product Line is intended to be used for measurements, data collection and analysis of lung function (PFT) and cardio-pulmonary (CPET) parameters, aiding in the diagnosis of related conditions. The results of the test can be viewed online with the help of a computer screen and can be printed after the test. The test results can be saved for future reference or report generation purposes.

The products can be utilized with patients age 4 years and older as long as they can cooperate in the performance - no special limit to patient's sex or height exists. Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities).

A qualified physician has to reassess all Vyntus/SentrySuite measurements. An interpretation by Vyntus/SentrySuite is only significant if it is considered in connection with other clinical findings.

Additional for Vyntus ECG:

The Vyntus ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-lead ECGs are analyzed automatically and suggestions for the interpretation of the resting ECG can be made by the software. ECG interpretation statements made by the Vyntus/ SentrySuite represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements.

The Vyntus ECG can be used for non-interpretive applications in patients age 4 years and older and a weight of 20 kg or higher. The Vyntus ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital). The Vyntus ECG is not intended for intracranial use. The Vyntus ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The Vyntus ECG is not intended for use in home healthcare environments. Automatic interpretation of the ECG is not possible for pediatric and adolescent patients below 16 years of age and for patients with pacemakers.

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

I. Type of Submission

Traditional 510(k)
Date Prepared: August 21, 2019

II. Submitter

Name: **Vyaire Medical GmbH**
Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Official Correspondent	Elmar Niedermeyer	**US Agent**	Colleen Watson
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E-mail	elmar.niedermeyer@vyaire.com	E-mail:	Colleen.Okeeffe@vyaire.com

III. Establishment Registration Number

9615102

IV. Common Name or Classification Name

Pulmonary function data calculator (Primary)
(CFR 868.1880, Product Code BZC)
Electrocardiograph (Secondary)
(CFR 870.2340, Product Code DPS)

V. Trade Name

Vyntus/SentrySuite Product Line

VI. Device Classification

This is a Class II device

VII. Classification Panel

73 Anesthesiology Part 868 (Primary)
74 Cardiovascular Part 870 (Secondary)

VIII. Reason for Premarket Notification

New medical device, new option Hi/Lo FiO2, Software SentrySuite 3.0 (update)

IX. Legally predicate marketed devices

Vyntus / SentrySuite Product Line K150810 Code BZC, DPS
Predicate Device Company: Vyaire Medical GmbH

X. Reference Devices

Oxycon Pro K992214 Code BZC, DPS, MWI, MLC
Reference Device Company: Vyaire Medical GmbH

XI. Device Description

Option Hi/Lo FiO2: The High/low FiO2 option of the Vyntus CPX is designed to measure the ventilation and the gas exchange (O2 uptake, CO2 production) of a subject with varying inspiratory concentrations of O2.

XII. Indications for Use

The Vyntus/SentrySuite Product Line is intended to be used for measurements, data collection and analysis of lung function (PFT) and cardio-pulmonary (CPET) parameters, aiding in the diagnosis of related conditions. The results of the test can be viewed online with the help of a computer screen and can be printed after the test. The test results can be saved for future reference or report generation purposes.

The products can be utilized with patients age 4 years and older as long as they can cooperate in the performance - no special limit to patient's sex or height exists. Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities). A qualified physician has to reassess all Vyntus/SentrySuite measurements. An interpretation by Vyntus/SentrySuite is only significant if it is considered in connection with other clinical findings.

Additional for Vyntus ECG:

The Vyntus ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-lead ECGs are analyzed automatically and suggestions for the interpretation of the resting ECG can be made by the software. ECG interpretation statements made by the Vyntus/SentrySuite represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements. The Vyntus ECG can be used for non-interpretive applications in patients age 4 years and older and a weight of 20 kg or higher. The Vyntus ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities

(e.g. the doctor's office or hospital). The Vyntus ECG is not intended for intracranial use. The Vyntus ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The Vyntus ECG is not intended for use in home healthcare environments. Automatic interpretation of the ECG is not possible for pediatric and adolescent patients below 16 years of age and for patients with pacemakers.

XIII. Required Components

- Vyntus CPX / ECG with SentrySuite Software
- Instruction for Use
- Option Hi/Lo FiO2
    - HR-valve 2730 complete
    - Breathing bag
    - DVT complete for High / Low FiO2
    - Hans-Rudolph inhaler adapter
    - Filling assembly for bag

XIV. 5.14 Summary Table of Comparison

Comparison to predicate devices SentrySuite Product Line Predicate K150810 & Reference Device Oxycon Pro K992214			
	Oxycon Pro **K992214** **Reference Device**	**Vyntus/SentrySuite Product Line** **K150810** **Predicate**	**Vyntus/SentrySuite Product Line** (with Hi/Lo FiO2)
Indication for Use	Oxycon Pro is a software-driven medical device for exercise measurements, including ECG ST Segment Analysis and/or ECG Stress Analysis. It measures the human response to increasing workloads with emphasis on the gas exchange parameters. Measurements include ventilation, oxygen uptake, carbon dioxide excretion, heart rate and derived parameters. The results of the tests, including the ECG wave forms, can be viewed on the computer screen and can be printed during the test. The test results can be saved on the computer hard disk for further referral or report generation purposes. The Oxycon Pro interfaces to a test subject via mouthpiece or a face mask and ECG electrodes. The Oxycon Pro interfaces to a peripheral ergometer or treadmill. The patient population is 4 years and older. The Oxycon Pro is capable of performing computerized ECG interpretation during resting condition. The intended use locations are either in a physician office, hospital exercise rehabilitation facilities, or similar areas. It is intended to be used by or on the order of a physician or similar qualified health care professional. This device is intended for use in the hospital environment, physician's office, or similar settings. This device is not intended for home use.	The Vyntus/SentrySuite product line is intended to be used for measurements, data collection and analysis of lung function (PFT) and cardio-pulmonary (CPET) parameters, aiding in the diagnosis of related conditions. The results of the test can be viewed online with the help of a computer screen and can be printed after the test. The test results can be saved for future reference or report generation purposes. The products can be utilized with patients age 4 years and older as long as they can cooperate in the performance - no special limit to patient's sex or height exists. Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities). A qualified physician has to reassess all Vyntus/SentrySuite measurements. An interpretation by Vyntus/SentrySuite is only significant if it is considered in connection with other clinical findings. **Additional for Vyntus ECG:** The Vyntus ECG is intended for measuring the surface electro-cardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-lead ECGs are analyzed automatically and suggestions for the interpretation of the resting ECG can be made by the software. ECG interpretation statements made by the Vyntus/SentrySuite represent partial qualitative and quantitative information on the patient's cardiovas-cular condition and no therapy or drugs can be administered based solely on the interpretation statements. The Vyntus ECG can be used for non-interpretive applications in patients age 4 years and older and a weight of 20 kg or higher. The Vyntus ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by	**Identical** **(to Predicate K150810)**

		trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital). The Vyntus ECG is not intended for intracranial use. The Vyntus ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The Vyntus ECG is not intended for use in home healthcare environments. Automatic interpretation of the ECG is not possible for pediatric and adolescent patients below 16 years of age and for patients with pacemakers.	
Intended Patient population	The patient population is 4 years and older.	4 years and older and a weight of 20 kg or higher	**Identical (to Predicate K150810)**
Software Platform	JLab Software	SentrySuite Software	**Identical (to Predicate K150810)**
Software Version	JLab version 5.7	SentrySuite version 2.13	SentrySuite version 3.0
Perfor-mance (measuring programs)	• Slow Spirometry • Forced Spirometry • MVV • Breath-by-Breath • Indirect Calorimetry • Resting ECG • Stress ECG	• Slow Spirometry • Forced Spirometry • MVV • Breath-by-Breath • Indirect Calorimetry • Resting ECG • Stress ECG	**Identical**
	• High/Low FiO2	----------	**Identical (to Reference K992214)**
	• Intrabreath • Respiratory Drive P0.1 • Mixing Chamber	----------	----------
Perfor-mance (technical data and accuracy)	**Flow measurement** Range: 0 – 15 L/s Accuracy: 70 mL/s or 3% **Volume measurement** Range: 0 – 10 L Accuracy: 50 mL or 2% **Ventilation** Range: 0 – 300 L/min Accuracy: 0.05 L/min or 2% **V'O2, V'CO2** Range: 0 – 7 L/min Accuracy: 0.05 L/min or 3% **RER** Range: 0.6 – 2.0 Accuracy: 4%	**Flow measurement** Range: 0 – 15 L/s Accuracy: 70 mL/s or 3% **Volume measurement** Range: 0 – 10 L Accuracy: 50 mL or 2% **Ventilation** Range: 0 – 300 L/min Accuracy: 0.5 L/min or 2% **V'O2, V'CO2** Range: 0 – 7 L/min Accuracy: 0.05 L/min or 3% **RER** Range: 0.6 – 2.0 Accuracy: 4%	**Identical**
	Hi/Lo Fi O2 Premixed inspiratory gases up to 100% O2 from manually filled bag	----------	**Identical (to Reference K992214)**

Sterilization	The device along with its accessories is neither supplied sterile nor intended to be sterilized	The device along with its accessories is neither supplied sterile nor intended to be sterilized	**Identical**

Summary of technological characteristic compared to the predicate / reference device to the table above:

- The new Vyntus/SentrySuite Product Line with option Hi/Lo FiO2 is identical in indication for use compared to the predicate Vyntus/SentrySuite Product Line K150810.
- The patient population for the proposed device is identical to the predicate device Vyntus/SentrySuite Product Line with K150810.
- The Software platform for the proposed device is identical to the predicate Vyntus/SentrySuite Product Line K150810. Both devices use the software SentrySuite and differ only in software version. The software version for the proposed device is the SentrySuite version 3.0.
- The measuring programs & accuracy of the proposed device are identical to the predicate device. Except the new measurement Hi/Lo FiO2 is identical to the reference device Oxycon Pro K992214.

XV. Summary of Device Testing

Non-clinical tests conducted for determination of substantial equivalence:

Characteristic	Standard/Test	Results Summary
1. Basic Safety	IEC 60601-1	The proposed device passes the applicable tests and standards
2. EMC Compatibility	IEC 60601-1-2	The proposed device passes the applicable tests and standards
3. Risk Management	ISO 14971	The proposed device passes the applicable tests and standards
4. Usability	EN 62366	The proposed device passes the applicable tests and standards
5. Software life cycle	ISO 62304	The proposed device passes the applicable tests and standards
6. Biocompatibility	ISO 10993-1	The proposed device passes the applicable tests and standards
7. Accuracy Testing	Accuracy of measurement	The proposed device passes the applicable tests and standards
Summary Discussion of Bench Performance Data		
The Vyaire Medical GmbH Vyntus/SentrySuite Product Line with the option Hi/Lo FiO_2 passed all specified test requirements. The validation and verification testing confirmed this device with the option Hi/Lo FiO2 meets user needs and design inputs for PFT and CPET. Testing also confirmed physical attributes and device performance meet the requirements of the standards listed in the performance testing summary above. These standards address basic safety, EMC compatibility, risk management, usability, software life cycle and biocompatibility. All testing which have been performed demonstrate substantial equivalence to the predicate devices.		

Clinical tests conducted for determination of substantial equivalence and/or of clinical information:

Clinical Performance Data/Information:
Clinical testing was not performed with this device.

Conclusion drawn from non-clinical and clinical data:

The Vyaire Medical GmbH CPET system with the new option Hi/Lo FiO2 meets the functional claims and intended use as described in the product labeling. The Vyntus/SentrySuite Product Line is substantially equivalent to the predicate devices described in the submission.

XVI. Conclusion

Based on the above, Vyaire Medical GmbH concludes that the Vyntus/SentrySuite Product Line with the new option Hi/Lo FiO2 is substantially equivalent to the legally marketed predicate devices.