August 16, 2019

Vyaire Medical Inc.
Colleen Watson
Director, Regulatory Affairs
26125 N. Riverwoods Blvd.
Mettawa, Illinois 60045

Re: K190853
Trade/Device Name: Vyntus BODY
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-function data calculator
Regulatory Class: Class II
Product Code: BZC, JEH, BTY
Dated: July 15, 2019
Received: July 17, 2019

Dear Colleen Watson:

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,

James Lee, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190853

Device Name
Vyntus BODY

Indications for Use *(Describe)*
The Vyntus BODY is intended to be used for measurements, data collection and analysis of lung function (PFT) parameters, aiding in the diagnosis of related conditions. All the measurements are performed via a mouthpiece, a mask or nasal adapters. 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 aged 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 BODY measurements. An interpretation by SentrySuite is only significant if it is considered in connection with other clinical findings.

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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510(k) Summary

I. Submitter

Vyaire Medical, Inc.
26125 N. Riverwoods Blvd.
Mettawa, IL 60045

Contact Person: Colleen Watson
Phone: + 847-786-5998 x110070
Date Prepared: August 14, 2019

II. Device

Device Proprietary Name:	Vyntus BODY
Common or Usual Name:	Pulmonary-function data calculator Volume Plethysmograph Predictive Pulmonary Function Value Calculator
Classification Name:	Pulmonary-function data calculator Volume Plethysmograph Predictive Pulmonary Function Value Calculator
Regulation Number:	21 CFR 868.1880 21 CFR 868.1760 21 CFR 868.1890
Product Code:	BZC, JEH, BTY
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate: SentrySuite Product Line, K122699, CareFusion Germany 234 GmbH
- Secondary Predicate: Vyntus ONE, K181524, Vyaire Medical Inc.

IV. Device Description

The Vyntus BODY is a whole-bodyplethysmograph and consists of the Vyntus BODY cabin, an ultrasonic flow sensor (USS), and a shutter. The Vyntus BODY system allows the determination of a subjects' pulmonary function status. It includes the determination of the subjects' ventilatory flows and volume by means of the USS. The measurement of the lung diffusion by the DLCO technique is accomplished with the supply of test gas and the gas analyzers for methane (CH4) and carbone monoxide (CO).

All variants are stationary and not battery operated. The sensor data is sent to a host computer system via cable connection for processing, storage, and reporting. The host computer can be networked via LAN, WLAN, or Internet.

All measurements are performed with the use of the Windows based operating software SentrySuite (SeS). The SeS software also stores the measurement results and provides output capabilities.

The host computer, monitor, and printer are mounted on the Vyntus Cart. Use of the cart is optional; computing equipment may be placed on other furniture.

V. Indications for Use

The Vyntus BODY is intended to be used for measurements, data collection and analysis of lung function (PFT) parameters, aiding in the diagnosis of related conditions. All the measurements are performed via a mouthpiece, a mask or nasal adapters. 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 further referral or report generation purposes.

The products can be utilized for patients from 4 years on and older as long as they can cooperate in the performance – no special limit to patient’s sex or height.

Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar settings (professional healthcare facilities).

A qualified physician has to reassess all Vyntus BODY measurements. An interpretation by SentrySuite is only significant by confirmation of other clinical findings.

VI. Comparison of Technological Characteristics

The subject device and predicate devices share the following technological characteristics:

- software network options;
- measuring programs;
- patient user interface and associated specification;
- patient direct contacting parts;
- gases used;
- sensor technologies;
- environmental operating conditions; and
- accessories.

The subject body and predicate devices are technologically different as follows:

- minor differences in hardware components including cabin design, trolley, and diffusion option; and
- use of different software version.

A comparison of the Vyntus BODY to the predicate devices is provided below.

		Vyntus BODY (Subject Device)	**SentrySuite Product Line (K122699)**	**Vyntus ONE (K181524)**	**Comparison**
Use setting		Healthcare setting	Healthcare setting	Healthcare setting	Identical
Patient population		Patients > 4 years old	Patients > 4 years old	Patients > 4 years old	Identical
Hardware Components	Cabin	Frame: aluminum Windows: glass Volume: 1110 L Locking Mechanism: electromagnetic Electronics: built into the cabin ceiling	Frame: aluminum Windows: acrylic glass Volume: 830 L Locking Mechanism: mechanical Electronics: built into the cabin floor	N/A	Different
	Patient User Interface	Ultrasonic flow sensor (ultrasonic signal) Flow Path Valve	Pneumotach (pressure difference to detect flow) Cross adapter Shutter	Ultrasonic flow sensor (ultrasonic signal) Flow Path Valve	Identical to K181524
	Trolley	Vyntus CART 3b	Trolley E	Vyntus CART 3.0N Vyntus CART 3.1N	Different
	Diffusion Option	Diffusion Real Time unit (covered in the cabin ceiling)	Diffusion Real Time unit (mounted in the box frame)	Diffusion Real Time unit (covered in the Vyntus ONE unit)	Different
		Demand Valve (to supply gas)	Demand Valve (to supply gas)	Electronic demand valve (to supply gas)	Identical to K122699
Software		SentrySuite Version 2.19	SentrySuite Version 2.7	SentrySuite 2.21	Different
Software Network Options		• Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Sentry.NET • Data integration • Database handling • JINET server	• Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Sentry.NET • Data integration • Database handling • JINET server	• Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Sentry.NET • Data integration • Database handling • JINET server	Identical
Performance (Measuring programs)		• Slow Spirometry (ERV, IC, VCin, VCex) • Incentive Spirometry (animation)	• Slow Spirometry (ERV, IC, VCin, VCex) • Incentive Spirometry (animation)	• Slow Spirometry (ERV, IC, VCin, VCex) • Incentive Spirometry (animation)	Identical to K122699

	Vyntus BODY (Subject Device)	**SentrySuite Product Line (K122699)**	**Vyntus ONE (K181524)**	**Comparison**
	• Forced Spirometry (FVC, FEF1, PEF, MEF50, etc.) • MVV (MVV) • Bodyplethysmography (FRCpleth, TLC, RV, sRaw) • Diffusion SB Realtime (Vin, VA, TLC, FICO, FICH4, TLC-SB, FRC-SB, RV-SB DLCLO) • Diffusion SB Intrabreath (Vin, VA, TLC, FECO, FECH4) • R Occlusion (ROCC) • Respiratory Drive P0.1 (P0.1) • MIP / MEP (maximum mouth pressure in-expiratory in kPa) • Bronchoprovocation test	• Forced Spirometry (FVC, FEF1, PEF, MEF50, etc.) • MVV (MVV) • Bodyplethysmography (FRCpleth, TLC, RV, sRaw) • Diffusion SB Realtime (Vin, VA, TLC, FICO, FICH4, TLC-SB, FRC-SB, RV-SB DLCLO) • Diffusion SB Intrabreath (Vin, VA, TLC, FECO, FECH4) • R Occlusion (ROCC) • Respiratory Drive P0.1 (P0.1) • MIP / MEP (maximum mouth pressure in-expiratory in kPa) • Bronchoprovocation test	• Forced Spirometry (FVC, FEF1, PEF, MEF50, etc.) • MVV (MVV) • Diffusion SB Realtime (Vin, VA, TLC, FICO, FICH4, TLC-SB, FRC-SB, RV-SB DLCLO) • Diffusion SB Intrabreath (Vin, VA, TLC, FECO, FECH4) • R Occlusion (ROCC) • Respiratory Drive P0.1 (P0.1) • MIP / MEP (maximum mouth pressure in-expiratory in kPa)	
Patient User Interface Specifications	• Flow Accuracy (exhalation): 0 - 14 L/S: 1.5% or 0.05 L/S (whichever is greater) • Flow Accuracy (inhalation): 0 to 14 L/S: 2.5% or 0.05 L/S (whichever is greater) • Flow Range: 0 - 18 L/S bidirectional • Flow Resolution: 1mL/s • Volume Accuracy (exhalation): 0 to 14L: 1.5% or 0.05L (whichever is greater) • Volume Accuracy (inhalation): 0 to 14L: 2.5% or 0.05L (whichever is greater) • Volume Range: +/- 30 L (software limited)	• Flow Accuracy (exhalation): 0.2 - 12 L/S: +/- 2% or +/- 0.2 L/S (whichever is greater) • Flow Accuracy (inhalation): 0.1 - 14 L/S: +/- 5% or +/- 0.2 L/S (whichever is greater) • Flow Range: 0 - +/- 20 L/S • Flow Resolution: 10 mL/s • Volume Accuracy (in/ex): 0.5 to 8L: +/- 3% or +/- 0.05L (whichever is greater) • Volume Range: +/- 20 L • Volume Resolution: 1 mL	• Flow Accuracy (exhalation): 0 - 14 L/S: 1.5% or 0.05 L/S (whichever is greater) • Flow Accuracy (inhalation): 0 to 14 L/S: 2.5% or 0.05 L/S (whichever is greater) • Flow Range: 0 - 18 L/S bidirectional • Flow Resolution: 1mL/s • Volume Accuracy (exhalation): 0 to 14L: 1.5% or 0.05L (whichever is greater) • Volume Accuracy (inhalation): 0 to 14L: 2.5% or 0.05L (whichever is greater) • Volume Range: +/- 30 L (software limited)	Identical to K181524

	Vyntus BODY (Subject Device)	**SentrySuite Product Line (K122699)**	**Vyntus ONE (K181524)**	**Comparison**
	• Volume Resolution: 1 mL		Volume Resolution: 1 mL	
Gases used for Vyntus BODY	Single Breath RT & Intrabreath 0.3 + 0.021% Methane (CH4) 0.3 + 0.021% Carbon Monoxide (CO) 21 + 1.47% Oxygen (O2) Rest: Nitrogen	Single Breath RT & Intrabreath 0.3 + 0.021% Methane (CH4) 0.3 + 0.021% Carbon Monoxide (CO) 21 + 1.47% Oxygen (O2) Rest: Nitrogen	Single Breath RT & Intrabreath 0.3 + 0.021% Methane (CH4) 0.3 + 0.021% Carbon Monoxide (CO) 21 + 1.47% Oxygen (O2) Rest: Nitrogen	Identical
Patient Direct Contacting Parts	• Single Use mouthpiece • Silicone mouthpiece • Nose clip • Nose clip pad • MicroGard II Filter	• Single Use mouthpiece • Silicone mouthpiece • Nose clip • Nose clip pad • MicroGard II Filter	• Single Use mouthpiece • Silicone mouthpiece • Nose clip • Nose clip pad • MicroGard II Filter	Identical
Sterilization	The device and accessories are provided non-sterile and are not intended for sterilization prior to use.	The device and accessories are provided non-sterile and are not intended for sterilization prior to use.	The device and accessories are provided non-sterile and are not intended for sterilization prior to use.	Identical
Energy	100 – 240 V/ 50 – 60 Hz	100 – 240 V/ 50 – 60 Hz	100 – 240 V/ 50 – 60 Hz	Identical
Electrical Safety	Class I protection	Class I protection	Class I protection	Identical
Environmental Operating Parameters	Temperature: +10° to 34°C Relative humidity: 20 to 80%, non-condensing Barometric pressure: 700 -1060 hPa	Temperature: +10° to 34°C Relative humidity: 15 to 95%, non-condensing Barometric pressure: 700 - 1060 hPa	Temperature: +10° to 34°C Relative humidity: 20 to 80%, non-condensing Barometric pressure: 700 -1060 hPa	Different

		Vyntus BODY (Subject Device)	SentrySuite Product Line (K122699)	Vyntus ONE (K181524)	Comparison
Accessories	General	• Silicone mouthpiece for children • Silicone mouthpiece • Plastic mouthpiece • Manual calibration syringe, 1L • Manual calibration syringe, 3L Silicone sleeve, 60 mm for manual calibration syringe, 3 L • Silicone adapter “Oval” for MicroGard IIB • Adapter ID 3 • Nose-clip “plastic” • Nose-clip pad “foam material” • MicroGard IIC • MicroGard IIB with integrated mouthpiece • Filter kit MicroGard type IIB • Filter kit MicroGard type IIC • Nebulizer end cap Medic-Aid • Drying Tube ME series 48 inch • Silicone mouthpiece FreeFlow™ • Mouthpiece (disposable mouthpiece blue) • Nose-clip disposable	• Silicone mouthpiece for children • Silicone mouthpiece • Plastic mouthpiece • Manual calibration syringe, 1L • Manual calibration syringe, 3 L • Silicone sleeve, 60 mm for manual calibration syringe, 3L • Silicone adapter “Oval” for MicroGard IIB • Adapter ID 3 Nose-clip “plastic” • Nose-clip pad “foam material” • MicroGard IIC • MicroGard IIB with integrated mouthpiece Filter kit MicroGard type IIB • Filter kit MicroGard type IIC • Nebulizer end cap Medic-Aid • Drying Tube ME series 48 inch	• Silicone mouthpiece for children • Silicone mouthpiece • Plastic mouthpiece • Manual calibration syringe, 1L • Manual calibration syringe, 3 L • Silicone sleeve, 60 mm for manual calibration syringe, 3 L • Silicone adapter “Oval” for MicroGard IIB • Nose-clip "plastic" • Nose-clip pad "foam material" • MicroGuard IIC • MicroGard IIB with integrated mouthpiece • Filter kit MicroGard type IIB • Filter kit MicroGard type IIC • Nebulizer end cap Medic-Aid • Drying Tube ME series 48 inch • Silicone mouthpiece FreeFlow™ • Mouthpiece (disposable mouthpiece blue) • Nose-clip disposable	Identical to K181524

		Vyntus BODY (Subject Device)	SentrySuite Product Line (K122699)	Vyntus ONE (K181524)	Comparison
	Patient User Interface Accessories	• USS Module with adapter and prot. cover • USS MicroGard Adapter • Cable port protective cover • FPV block • FPV shutter mechanism • FPV silicone valves • FPV X-Ring Kit consists of 3 x X-ring and 1 x small rod • USS Module holder • FPV block holder • Disinfection tray insert • USS MicroGard Adapter for gas sampling	N/A	• USS Module with adapter and prot. cover • USS MicroGard Adapter • Cable port protective cover • FPV block • FPV shutter mechanism • FPV silicone valves • FPV X-Ring Kit consists of 3 x X-ring and 1 x small rod • USS Module holder • FPV block holder • Disinfection tray insert • USS MicroGard Adapter for gas sampling	Identical to K181524

Discussion:

As seen above, differences between the subject and predicate devices include minor differences in hardware components and use of a different software version.

These technological differences do not create new questions of safety and effectiveness and are addressed by the testing described below. In addition, the general accessories were previously cleared under K181884 and K122699.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- Electrical safety and EMC per IEC 60601-1:2005 and IEC 60601-2:2014;
- Usability per IEC 62366:2007;
- Software validation per IEC 62304:2006;
- Accuracy testing;
- Climatic testing; and
- ATS/ERS Task Force: Standardization of Lung Function Testing

VIII. Conclusion

The information provided above supports that the Vyntus BODY is substantially equivalent to the predicate devices. Although minor differences in design and technology exist between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the Vyntus BODY is substantially equivalent to the predicate devices.