November 30, 2018

Vyaire Medical, Inc.
Elmar Niedermeyer
Manager, Regulatory Affairs
Leibnizstrasse 7
Hoechber, 97204 De

Re: K181524
Trade/Device Name: Vyntus ONE
Regulation Number: 21 CFR 868.1880
Regulation Name: Pulmonary-Function Data Calculator
Regulatory Class: Class II
Product Code: BZC, DPS
Dated: October 31, 2018
Received: November 2, 2018

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/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,

James J. Lee -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181524

Device Name
Vyntus ONE

Indications for Use *(Describe)*

The Vyntus ONE / 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 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 / SentrySuite measurements. An interpretation by Vyntus ONE / 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

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 2018/05/24

5.2 Submitter

Name: **Vyaire Medical, Inc.**
(Doing business as CareFusion Germany 234 GmbH)

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

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

5.5 Trade Name

Vyntus ONE

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

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

5.8 Reason for Premarket Notification

- new medical device

5.9 Legally predicate marketed devices

- Vyntus / SentrySuite Product Line K150810 Code BZC, DPS

  Predicate Device Company:
  Vyaire Medical, Inc. (Doing business as CareFusion Germany 234 GmbH)

5.10 Reference Devices

- SentrySuite Product line K122699 Code BZC, JEH, BZG, BTY
- MasterScreen Pneumo - USS K071753 Code BTY
- Vmax Series K942211 Code BTY

  Reference Device Company:
  Vyaire Medical, Inc. (Doing business as CareFusion Germany 234 GmbH)

5.11 Device Description

Description & function:
The Vyntus ONE is a full pulmonary function test (PFT) system, consisting of a main unit with the gas analyzers and electronics inside, a patient interface with a Flow Path Valve eDemand and an electronic demand valve inside and an ultrasound flow sensor (USS). The entire equipment is mounted on a cart which includes the isolation transformer and the support arm for the patient interface and the USS.

The Vyntus ONE is connected via USB interface to the desktop PC and enables the following standard measurements:
• Diffusion SB Realtime
• Diffusion SB Intra-breath
• FRC N2 washout
• Slow/forced spirometry and MVV

The Vyntus ONE also supports cardiopulmonary exercise testing (CPET). The specific hardware consists of the light-weight digital volume transducer (DVT) and an optional SpO2 pulse oximeter. It enables the following standard measurement features:
• Breath-by-breath (BxB) gas exchange
• Workload control for bicycle ergometer or treadmills
• Automatic workload protocols

Further optional hardware and software include:
• Vyntus ECG: 12-lead Electrocardiogram (ECG) recording (resting and stress ECG)
• ROcc, P0.1, MIP / MEP measurements

5.12 Intended Use Statement

The Vyntus ONE / 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 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 / SentrySuite measurements. An interpretation by Vyntus ONE / 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.

5.13 Required Components

- PC
- CART 3.0N / 3.1N
- Vyntus ONE main unit
- USS module
- FPV (Flow Path Valve)
- Control Unit FPV eDemand
- Vyntus ECG
- SentrySuite Software
- Instruction for Use
- Accessories

5.14 Summary Table of Comparison

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
Indication for Use	Pulmonary function testing	----------	----------	----------	Identical
Target population	4 years on and older	----------	----------	----------	Identical
Software used	SentrySuite (Version 2.13)	----------	----------	----------	SentrySuite (Version 2.21)
Software Network options	• Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Sentry.NET (mobile Review) • Data integration • Database handling • JINET server	----------	----------	----------	Identical
Performance (measuring programs)	• Slow Spirometry • Incentive Spirometry • Forced Spirometry • MVV	• Slow Spirometry • Incentive Spirometry • Forced Spirometry • MVV	----------	----------	Identical
	----------	• Diffusion SB Realtime • Diffusion SB Intrabreath • R Occlusion • Respiratory Drive P0.1 • MIP / MEP	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
Performance (measuring programs)	• Breath-by-breath (BxB) • Resting ECG • Stress ECG • Indirect Calorimetry	----------	----------	----------	Identical
	----------	----------	• Functional Residual Capacity (FRC) by Nitrogen (N2) washout	----------	Identical
Patient direct contacting parts	• Full face CPET masks • Single Use mouthpiece • Silicone mouthpiece • Nose clip • Nose clip pad • Head gear	----------	----------	----------	Identical
	----------	• Single Use mouthpiece • Silicone mouthpiece • Nose clip • Nose clip pad • MicroGard II Filter	----------	----------	Identical
Biocompati-bility	Patient user interface • Digital Volume Transducer • Full face CPET mask	----------	----------	----------	Identical
	----------	----------	----------	Patient user interface • ultrasonic flow sensor • Shutter	Patient user interface • ultrasonic flow sensor (new material) • Flow Path Valve (new material)
Sterilization	The device along with its	----------	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	accessories is neither supplied sterile nor intended to be sterilized				
Cleaning Validation	Validation of Instrument disinfection & Surface disinfection	----------	----------	----------	Validation according FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Human factors	Usability testing acc. IEC 60601-1-6 and related IEC 62366; Usability Engineering File & Usability report	----------	----------	----------	Usability testing acc. IEC 60601-1-6 and related IEC 62366; Usability Engineering File & Usability report
Energy used	100 – 240V / 50 – 60Hz	----------	----------	----------	Identical
Patent user Interface technique	• Digital Volume Transducer technique	----------	----------	----------	Identical
	----------	----------	----------	• ultrasonic flow sensor technique	Identical
Patient user Interface Specification	**Digital Volume Transducer** • Flow: 0 – 15 L/s (3%) • Volume: 0 – 10 L (2%) • Resolution: 3ml • Resistance: <0.1 kPa/L/s at 15 L/s • ATS compliant	----------	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	----------	**Pneumotachograph** • Flow Accuracy (exhalation) 0,2 to 12 L/S: +/- 2% or +/- 0,2 L/S (whichever is greater) • Flow Accuracy (inhalation) 0,1 to 14 L/S: +/- 5% or +/- 0,2 L/S (whichever is greater) • Flow Range 0 to +/- 20 L/S • Flow Resolution 10ml/s • Volume Accuracy 0,5 to 8L: +/- 3% or +/- 0,05L (whichever is greater) • Volume Range +/- 20 L • Volume Resolution 1ml	----------	----------	**Ultrasonic Flow Sensor** • Flow Accuracy (exhalation) 0 to 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 to 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) • Volume Resolution 1ml
Electrical Safety	Protection class I	----------	----------	----------	Identical
Environmental Specification	• Temperature: +10° to 34°C • Relative humidity: 15 to 95%, non condensing • Barometric pressure: 700 to 1060 hPa	----------	----------	----------	• Temperature: +10° to 34°C • Relative humidity: 20 to 80%, non condensing • Barometric pressure: 700 to 1060 hPa

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
Accessories listed in User Manual	**892102** Silicone mouthpiece for children **892100** Silicone mouthpiece **720254** Manual calibration syringe 3l **852740** Silicone sleeve, 60 mm for manual calibration syringe 3l **S773470** Silicone mouthpiece FreeFlow™, 12 pieces **V-892894** Mouthpiece (disp. mouthpiece blue), 180 pieces **892120** Nose-clip “plastic” **892121** Nose-clip pad “foam material”, 100 pieces **S42101** Nose-clip disposable, 10 pieces **S761889** Nose-clip disposable, 100 pieces **V-707326** Volume sensor DVT (digital volume transducer) complete **982094** Volume sensor insert **V-707725** Volume sensor insert **923015** O2 fuel cell **992582** Ear clip sensor for SpO2	----------	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	(Nonin Model 8000Q2) (applied part) **992506** SpO2 Flex sensor with cable for adults (Nonin Model 8000J-3) (applied part) **992578** Adult Flexi Wrap adhesive tape for Flex Sensor (pack of 25 pcs.) (Nonin Model 8000JFW) (applied part) **V-992528** SpO2 Reflectance Forehead Sensor (Nonin Model 8000R) **V-992529** SpO2 Reflect Sensor holder (Nonin Model 8000H) (applied part)				
	----------	**892103** Plastic mouthpiece, single use, 25 pieces **720252** Manual calibration syringe 1l **V-861449** Silicone adapter “Oval” for MicroGard IIB **852353** Adapter ID 30 **V-892384** MicroGard IIC, 50 pieces **V-892381** MicroGard IIB with integrated mouthpiece, 50 pieces **V-892391** Filter kit MicroGard type IIB, 80 pieces **V-892392** Filter kit MicroGard type IIC,	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
		80 pieces			
	---	---	---	---	**Additional Accessories "International Items"** **V-892895** Nose Clip (reusable), 5 pieces (applied part) **V-892900** Nose Clip (disposable), 10 pieces (applied part)

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	----------	----------	----------	----------	**Additional Accessories "PFT tests"** **V-707377** USS Module with adapter and prot. Cover **V-707380** USS MicroGard Adapter **V-707381** USS MicroGard Adapter for gas sampling **V-707722** Sample line Vyntus ONE **V-707384** Cable port protective cover, 5 pieces **V-707721** FPV block eDemand **V-707388** FPV shutter mechanism **V-707390** FPV silicone valves, 5 pieces **V-707383** USS Module holder **V-707393** FPV block holder **V-707394** Disinfection tray insert

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	----------	----------	----------	----------	**Additional Accessories "CPET tests"** **V-861078** Adapter Jaeger cone for DVT Vyntus ONE **V-841188** Calibration gas holder (0.8/0.38L) **706183** Gas bottle wall mount **V-992512** Nonin XPOD 3011 LP w. ODU
					Additional Accessories "CPET masks"
	V-982181 Headgear Oro Nasal Mask 7450 V2 Size L (applied part) **V-892180** Headgear Oro Nasal Mask 7450 V2 Size M (applied part)	----------	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	----------	----------	----------	----------	**V-982186** CPET Mask 7450 V2, Size L, Complete (applied part) **V-982185** CPET Mask 7450 V2, Size M, Complete (applied part) **V-892184** CPET Mask 7450 V2, Size S, Complete (applied part) **V-982187** CPET Mask 7450 V2, Size XS, Complete (applied part) **V-982188** CPET Mask 7450 V2, Size Petite, Complete (applied part) **V-982192** Flexible mask adapter **V-982189** Headgear Oro Nasal Mask 7450 V2 Size ES and Petite (applied part) **V-982195** Brace Set, Size L, for CPET Mask 7450 V2 **V-982196** Brace Set, Size M, for CPET Mask 7450 V2 **V-982197** Brace Set, Size S, for CPET Mask 7450 V2 **V-982198** Brace Set, Size XS, for CPET Mask 7450 V2 **V-982199** Brace Set, Size Petite, for CPET Mask 7450 V2 **V-982179** Oro Nasal 6450 V2 DISP

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
					with HG Size L 18ea/bx (disposable mask) (applied part) **V-982178** Oro Nasal 6450 V2 DISP with HG Size M 18ea/bx (disposable mask) (applied part) **V-982177** Oro Nasal 6450 V2 DISP with HG Size S 18ea/bx (disposable mask) (applied part) **V-982182** Oro Nasal 6450 V2 DISP with HG Size ES 18ea/bx (disposable mask) (applied part) **V-982183** Oro Nasal 6450 V2 DISP with HG Size Petite 18ea/bx (disposable mask) (applied part)
	Additional Accessories "Vyntus ECG" **992368** Disposable electrodes (Rest), 50 pieces (applied part) **892205** Disposable electrodes (Stress), 25 pieces (applied part) **806502** 1.5V AA battery "Varta Industrial" **V-806520** NiMH rechargeable battery	----------	----------	----------	Identical

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
	1.2 V AA ≥ 2500 mAh **V-996146** NiMH battery charger **V-841234** Bag for the Vyntus ECG, 25 pieces				
	----------	----------	----------	----------	**Additional Accessories "Other"** **S760707** Power line US AWG16 acc. To UL and CSA **918100** Power line EU H05 VV-F3G acc. to IEC 227 and IEC 245 **845117** Instrument tub with lid, 210 x 110 x 35 mm
	----------	----------	----------	----------	**Additional Accessories "IT components"** **V-991090** DELL Monitor 24" **V-991093** Monitor 24" **V-991091** Monitor 34" **V-994185** Dell Optiplex 3040MFF **V-994187** Dell Optiplex 3050MFF **V-994225**

	Vyntus / SentrySuite Product Line K150810 (Predicate device)	**SentrySuite Product Line K122699** (Reference device)	**Vmax K942211** (Reference device)	**MasterScreen Pneumo K071753** (Reference device)	**Vyntus ONE** (new device)
					Dell Optiplex 7050MFF **V-991481** HP Printer 6230e **V-994191** Notebook E5570 **V-994205** Notebook E5580

Summary of technological characteristics compared to the predicate device to the table above:

- The software platform used for the Vyntus ONE is equivalent to the predicate device Vyntus/SentrySuite Product line K150810. The software which is used is the SentrySuite software only with a different version.
- The Biocompatibility for the patient interface for Vyntus ONE and the reference device K071753 is equivalent as the new Vyntus ONE patient interface material has been tested completely according ISO 10993 standard. The following testing was done.
  Biocompability:
  Cytotoxiticity, sensitization, irritation, intracutaneous reactivity, acute systemic toxicity, material mediated pyrogenicity
  Chemical Characterization:
  Exaggerated Extraction
  FTIR
  HPLC-MS / UPLC-MS
  GC-MS Headspace
  GC-MS
  ICP-MS
  ICP-OES
- The specification for the patient user interface is equivalent to the reference device K122699. There is an insignificant difference in flow accuracy, flow resolution, volume accuracy. There is also an insignificant difference in flow range and volume range. The proposed device is more accurate in flow and volume and has a higher flow resolution. The difference in flow range and volume range is insignificant as the ranges are higher than a patient can breathe. The shift of the ranges and the improvements in the measurement details are caused in the technology improvement by using an ultrasonic flow measurement. The new technology improved the accuracy and maximum ranges slightly, as the flow resistance is lower in the subject device compared to the predicate device. Both systems fulfill the ATS/ERS standard “ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING”. The Vyntus ONE works as intended.
- The environmental conditions are nearly equivalent to the predicate device Vyntus/SentrySuite Product line. The testing supported that the subject device is as safe and effective as the predicate device.
- The accessories for the Vyntus ONE are in partially new compared to the predicate and reference devices.
  The new accessories which come into direct or indirect contact are:
  V-892895 Nose clip (reusable)
  V-892900 Nose clip (disposable)
  V-707377 USS module with adapter
  V-707380 USS MicroGard adapter
  V-707381 USS MicroGard adapter for gas sampling
  V-707721 FPV block eDemand
  V-707388 FPV shutter mechanism
  V-707390 FPV silicone valves, 5 pieces
  V-861078 Adapter Jaeger cone for DVT Vyntus ONE
  Performance testing supported that the subject device is as safe and effective as the predicate device.

5.15 Summary of Device Testing

1. Non-clinical tests conducted for determination of substantial equivalence:

Characteristic	Standard/Test	Results Summary
1. Risk Management	ISO 14971	The proposed device passes the applicable tests and standards
2. Usability	EN 62366	The proposed device passes the applicable tests and standards
3. Software life cycle	ISO 62304	The proposed device passes the applicable tests and standards
4. Basic Safety	IEC 60601-1	The proposed device passes the applicable tests and standards
5. EMC Compatibility	IEC 60601-2	The proposed device passes the applicable tests and standards
6. Biocompatibility	ISO 10993	The proposed device passes the applicable tests and standards
7. Accuracy Testing	Measurement effective-ness & accuracy	The proposed device passes the applicable tests and standards
8. Climatic Chamber test	Environmental testing according specifications	The proposed device passes the applicable tests and standards
9. ATS / ERS	Standard for lung function testing	The proposed device passes the applicable tests and standards

Summary Discussion of Bench Performance Data

The Vyntus ONE passed all specified test requirements.
The validation and verification testing confirmed this device meets user needs and design inputs for a pulmonary function testing system.
Testing also confirmed physical attributes and device performance meet the requirements of the standards listed in the performance testing summary above. These standards address risk management, usability, software life cycle, electrical safety, emc. biocompatibility, accuracy testing, climatic chamber testing and ATS / ERS. All testing which have been performed demonstrate substantial equivalence to the predicate devices.

2. 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.

3. Conclusion drawn from non-clinical and clinical data:

The Vyntus ONE meets the functional claims and intended use as described in the product labeling. The Vynuts ONE is substantially equivalent to the predicate device described in the submission.

5.16 Conclusion

Based on the above, Vyaire Medical concludes that the Vyntus ONE is substantially equivalent to the legally marketed predicate device and as safe as effective as the predicate.