DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 22,2014

CareFusion Germany 234 GmbH
Elmar Niedermeyer
Leibnizstrasse 7
Hoechberg, Bavaria, Germany 97204

Re: K133925
Trade/Device Name: Vyntus / SentrySuite Product line
Regulation Number: 868.1880
Regulation Name: Pulmonary-function data calculator
Regulatory Class: II
Product Code: BZC
Dated: July 22nd, 2014
Received: July 25th, 2014

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K

Device Name: Vyntus/SentrySuite product line

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).

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) Summary

## GENERAL INFORMATION

### 5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 12/13/2013

### 5.2 Submitter

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## 5.3 Establishment Registration Number

9615102

## 5.4 Common Name or Classification Name

Pulmonary-function data calculator
(CFR 868.1880, Product Code BZC)

## 5.5 Trade Name

Vyntus/SentrySuite Product line

## 5.6 Device Classification

This is a Class II device

## 5.7 Classification Panel

73 Anesthesiology Part 868 Code BZC

## 5.8 Reason for Premarket Notification

- New device

(The CareFusion CPET devices K072323 & K992214 have been revised with new hardware. The software platform SentrySuite has been taken over from SentrySuite Product line with 510(k) K122699)

## 5.9 Legally predicate marketed devices

- MasterScreen CPX K072323 Code BZC
- Oxycon Pro K992214 Code 73 BZC, 74 MWI, MLC, DPS
- SentrySuite Product line K122699 Code BTY, BZG, BZC, JEH

## 5.10 Predicate Device Company

- CareFusion Germany 234 GmbH

## 5.11 Device Description

Description & function:

The Vyntus CPX system is an accurate and reliable system that allows the determination of a subjects' metabolic response while exercising. It is a stationary, mains powered ergospirometry system. The system records the data breath-by-breath. The breath-by-breath data is collected through a facemask or mouth-piece and is sent to a host computer system via cable connection.

Scientific Concepts that form the basis of the device:

The digital volume transducer (DVT) measures the gas volume in- and expired. Gas samples are continuously drawn from a location very close to the mouth (between DVT and the face-mask or mouth-piece).

The gas samples are dryed by Nafion tubes and analyzed for $O_2$ and $CO_2$ content. From the breathing volume and the differences between inspiratory and expiratory $O_2$ and $CO_2$ concentrations the oxygen uptake and the $CO_2$ production ($V'O_2$ and $V'CO_2$) are calculated by the software.
The workload protocol selected by the user will control the ergometer device accordingly and the changes in the above vital signs due to the change in workload are recorded.
All data is stored together with the patient and test data in the database for later evaluation and printing.

Significant performance characteristics:

**Ergospirometry**

| Parameter | Measurement range | Accuracy |
|---|---|---|
| Ventilation(V'E) | 0 to 300 L/min | 2% or 0,5 L/min |
| O2 uptake (V'O2) | 0 to 7 L/min | 3% or 0,05 L/min |
| CO2 output (V'CO2) | 0 to 7 L/min | 3% or 0,05 L/min |
| RER | 0,6 to 2.0 | 4% or 0.04 |

**Volume Sensor**

| Parameter | Measurement range | Accuracy |
|---|---|---|
| Volume | 0 to 10 L | 2% or 50 mL |
| Flow | 0 to 15 L/s | 3% or 70 mL/s |

Resolution: 3 mL
Resistance: <0.1 kPa/L/s at 15 L/s
ATS-compliant

**Device Design:**
Vynuts CPX has been designed according CareFusion Standard Working Instruction 0301-5001-000-SWI (Design Control) into two configurations. This is the table top version and the cart version.

**Material used:**
- Vyntus CPX front panel [aluminium alloy 3.2315 EN-AW 6082]
- Vyntus CPX rear panel [aluminium alloy 3.3535 EN-AW5754]
- Vyntus CPX housing [babyblend FR3010 UL94V0]
- Vyntus CPX cart/corpus [steel panel alloy EN10130 DC01A]
- Vyntus CPX cart/spine [aluminium alloy AlMgSi 0,5 F22 (6066)]

**Physical properties:**
- size Vyntus CPX (31,94cm x 29,40cm x 13,57cm)
- weight Vyntus CPX (3995 gram)
- size cart (140cm x 70,90cm x 71,90cm)
- weight cart (86,4 kg)

## 5.12 Intended Use Statement

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).

## 5.13 Required Components

- PC or Notebook
- Vyntus CPX unit (table version)
- Vyntus table top power module
- DVT (Digital Volume Transducer)
- Ambient module
- USB cable (PC / Vyntus CPX unit)
- SentrySuite Software
- Instruction for Use
- Accessories
- Vyntus cart with power supply (optional)
- Polar receiver/belt for heart rate (optional)
- $SpO_2$ Nonin Xpod pulse oximeter (optional)
- External PC-based 8 Channel / 12 lead ECG (optional)
- Treadmill or bicycle ergometer (optional)

## 5.14 Summary Table of Comparison

| Comparison with MasterScreen CPX K072323 & Oxycon Pro K992214 | | | |
|---|---|---|---|
| | **Predicate CareFusion MasterScreen CPX K072323** | **Predicate CareFusion Oxycon Pro K992214** | **Vyntus CPX** (proposed device) |
| **Indication for Use** | The MasterScreen CPX stationary pulmonary function test system is a device which monitors the cardio-respiratory functions during stress testing, rehabilitation, sports medicine and other related activities. The MasterScreen CPX system allows the monitoring of metabolic parameters. The MasterScreen CPX system is intented to use with adults and children over the age of 14 years. | The 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.<br>The Oxycon Pro interfaces to a test subject via a mouthpiece or a face mask and ECG electrodes. The Oxycon Pro interfaces to a peripheral ergometer or treadmill. The patient population is 4 age and | 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.<br>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). |

| | | | |
|---|---|---|---|
| | | older.<br>The Oxycon Pro is capable of performing computerized ECG interpretation during resting condition.<br>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. | |
| **Intended patient population** | Adults and children over the age of 14 years | 4 years and older | **similar to K992214** |
| **Performance specification** | Flow: 0 – 15 L/s (3% or 70 ml)<br>Volume: 0 – 10 L (2% or 50 ml)<br>Ventilation:<br>0 – 300 L/m (2% or 0,5 L/min)<br>O2 uptake:<br>0 – 7 L/min (3% or 0,05 L/min)<br>CO2 output:<br>0 – 7 L/min (3% or 0,05 L/min)<br>RER: 0,6 – 2,0 (+4% or 0,04) | Flow: 0 – 15 L/s (3% or 70 ml)<br>Volume: 0 – 10 L (2% or 50 ml)<br>Ventilation:<br>0 – 300 L/m (2% or 0,5 L/min)<br>O2 uptake:<br>0 – 7 L/min (3% or 0,05 L/min)<br>CO2 output:<br>0 – 7 L/min (3% or 0,05 L/min)<br>RER: 0,6 – 2,0 (+4% or 0,04) | **similar** |
| **Gas sampling technique** | Breath-by-breath | Breath-by-breath | **similar** |
| **Patient contacting accessory** | • Face Mask<br>• Head strap for face mask<br>• Mouthpiece<br>• Nose clip<br>• ECG electrodes<br>• $SpO_2$ finger probe<br>• Polar sensor | • Face Mask<br>• Head strap for face mask<br>• Mouthpiece<br>• Nose clip<br>• ECG electrodes<br>• $SpO_2$ finger probe<br>• Polar sensor | **similar** |
| **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 | **similar** |
| **$O_2$ analyzer** | Electro-chemical<br>Range: 0 – 25%<br>Resolution: 0,01%<br>Accuracy: 0,05%<br>Response time: 80 ms<br>Life time: 2 years | Differential-paramagnetic principle high speed<br>Range: 0 – 25%<br>Resolution: 0,01%<br>Accuracy: 0,05%<br>Response time: 40 ms<br>Life time: 2 years | Electro-chemical high speed analyzer<br>Range: 0 – 25%<br>Resolution: 0,01%<br>Accuracy: 0,05%<br>Response time: 80 ms<br>Life time: 100 h or 1,5 years |
| **$CO_2$ analyzer** | Thermal conductive<br>Range: 0 – 10% | Infrared absorption principle<br>Range: 0 – 15% | Infrared absorption high speed analyzer |

| | | | |
|---|---|---|---|
| | Resolution: 0,01%<br>Accuracy: 0,05%<br>Response time: 80 ms<br>Life time: infinite | Resolution: 0,01%<br>Accuracy: 0,05%<br>Response time: 40 ms<br>Life time: infinite | Range: 0 – 15%<br>Resolution: 0,01%<br>Accuracy: 0,05% or 1%<br>Response time: 80 ms<br>Life time: infinite |
| **Options** | • Nonin Xpod pulse oximetry with oximeter probe intended to be clipped onto a finger or ear<br>• Polar heart rate receiver<br>• External PC-based 8-Channel/12 lead ECG<br>• Treadmill or bicycle ergometer | • Nonin Xpod pulse oximetry with oximeter probe intended to be clipped onto a finger or ear<br>• Polar heart rate receiver<br>• External PC-based 8-Channel/12 lead ECG<br>• Treadmill or bicycle ergometer | **similar to K072323** |
| **Environ-mental specifi-cations** | Operating:<br>+10 to +34 °C<br>30% to 95% RH<br>700 to 1060 hPa<br>Storage:<br>-30 to +50 °C<br>10% to 95% RH<br>600 to 1200 hPa | Operating:<br>+10 to +40 °C<br>15% to 95% RH<br>500 to 1150 hPa<br>Storage:<br>-20 to +50 °C<br>10% to 95% RH<br>600 to 1200 hPa | Operating:<br>+10 to +34 °C<br>20% to 80% RH<br>800 to 1060 hPa<br>Storage:<br>-20 to +50 °C<br>15% to 95% RH<br>600 to 1200 hPa |
| **Measur-ing programs** | • Slow Spirometry<br>• Forced Spirometry<br>• MVV<br>• Breath-by-Breath<br>• Indirect Calorimetry | • Slow Spirometry<br>• Forced Spirometry<br>• MVV<br>• Breath-by-Breath<br>• Indirect Calorimetry | **similar** |
| | | • Cardiac Output<br>• Cardiac Output<br>• High/Low FiO2<br>• Intrabreath<br>• End Tidal<br>• Respiratory drive<br>• P0.1<br>• Mixing Chamber<br>• Resting ECG<br>• Stress ECG | **----------** |

## Comparison with SentrySuite Product Line K122699

| | **SentrySuite Product Line K122699** | **Vyntus CPX** (proposed device) |
|---|---|---|
| **Software** | SentrySuite Software 2.x | **similar** |

| | | |
|---|---|---|
| **Software platform main features** | • can be installed on workstations in a network or stand alone<br>• can be used as a server in a network<br>• equipped with powerful SQL database<br>• connection to HIS<br>• complete seamless interfacing to hospital electronic medical record with VLINK<br>• with SentrySuite connectivity, patient data and measurement data can be exchanged between JAEGER JLAB, SensorMedics Vmax, Medical Graphics and nSpire<br>• software application for remote access with Sentry.NET like view, interpret and sign is possible<br>• data exchange via GDT to praxis systems and via HL7 for hospital systems<br>• remote applications with iPad / tablet like questionnaire | **similar** |

**Summary of technological characteristics compared to the predicate devices to the table above:**

- The Vyntus CPX is similar in indication for use compared to the predicate devices. The patient population is similar to the predicate CareFusion devise Oxycon Pro. It is 4 years and older and thereby the proposed device is substantial equivalent to the predicate device Oxycon Pro.
- The new high speed $O_2$ analyzer has a shorter life time compared to both predicate devices and also has a higher response time compared to the predicate Oxycon Pro K992214. The $O_2$ analyzer technique used for the Oxycon Pro is the differential-paramagnetic principle whereby the predicate MasterScreen CPX and the proposed device Vyntus CPX use electro-chemical analyzer technique. The advantage for exchanging the analyzers is that the $O_2$ analyzer in the proposed device Vyntus CPX can be exchanged by the user itself. With these insignificant changes the proposed device is substantial equivalent to the predicate devices.
- The new high speed $CO_2$ sensor works with infrared absorption technique and has an extended measuring range when compared to the predicate MasterScreen CPX K072323. Whereupon the predicate Oxycon Pro K992214 works with the similar infrared absorption technique as the proposed device but has a shorter response time. With this insignificant change the proposed device is substantial equivalent to the predicate devices.
- The environmental conditions are nearly similar to the predicate devices MasterScreen CPX and Oxycon Pro. There are only insignificant differences which will not have any influence on the device functions. The Vyntus CPX operates as intended in user environments. The proposed device is substantial equivalent to the predicate devices.
- The measuring programs of the proposed device are similar to the predicate device MasterScreen CPX and Oxycon Pro. The only difference is that Oxycon Pro has the possibility to do some more measurements. The Vyntus CPX measurements are substantial equivalent to the measurements of the predicate devices.
- The software platform for the Vyntus CPX is the powerful SentrySuite software from the predicate device “SentrySuite Product Line” K122699.

## 5.15 Summary of Device Testing

### 1. 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. ATS / ERS | Standard of lung function testing | 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. Accuracy Testing | Measurement effective-ness & accuracy according golden standard “Douglas bag” | The proposed device passes the applicable tests and standards |
| **Summary Discussion of Bench Performance Data** | | |
| The CareFusion Vyntus CPX cardio pulmonary exercise system passed all specified test requirements.<br>The validation and verification testing confirmed this device meets user needs and design inputs for a CPET system.<br>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, risk, usability, software life cycle, biocompatibility and environment. 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:<br><br>Clinical testing was not performed with this device. |

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

| |
|---|
| The Carefusion CPET system meets the functional claims and intended use as described in the product labeling. The Vynuts CPX is substantially equivalent to the K072323 MasterScreen CPX, K122699 SentrySuite Product line and K992214 Oxycon Pro described in the submission. |

## 5.16 Conclusion

Based on the above, CareFusion concludes that the Vyntus CPX is substantially equivalent to the legally marketed predicate device and performs at least as well or even better as the predicate devices.