



Food and Drug Administration
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August 14, 2015

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

Re: K150810

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 14, 2015
Received: July 17, 2015

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. 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 Industry and Consumer Education 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

 Kenneth J. Cavanaugh -S

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K150810

Page 1 of 1

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

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 16/03/2015

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)
Electrocardiograph
(CFR 870.2340, Product Code DPS)

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 (primary)
74 Cardiovascular Part 870 Code DPS (secondary)

5.8 Reason for Premarket Notification

- new medical device
- additional cart 3.0 to available cart 2.0

5.9 Legally predicate marketed devices

- MasterScope ECG K082539 Code BTY, DPS
- Cor12+ K091505 Code DSH
- Vyntus / SentrySuite Product line K133925 Code BZC

5.10 Predicate Device Company

- Cardinal Health Germany 234 GmbH (now CareFusion Germany 234 GmbH)
- Cardinal Health Germany 234 GmbH (now CareFusion Germany 234 GmbH)
- CareFusion Germany 234 GmbH

5.11 Device Description

Description & function:

The Vyntus ECG is the perfect 12-Lead PC-ECG extension for the Vyntus CPX via secure Bluetooth® communication. One integrated solution through the SentrySuite platform helps laboratories ease procedures and integration to reduce costs.

The Vyntus ECG records the full 12-lead resting and stress ECG via its wireless, battery operated ECG amplifier. The evaluation and interpretation is using the proven Hannover ECG System (HES).

Scientific Concept:

The surface electrodes of the Vyntus ECG record the electrical signals that are mainly generated by the heart muscle activity and repolarization. The small voltages are amplified and A/D converted. A low frequency high-pass filter is applied and the recorded signals are transmitted to the PC for recording, storing, evaluation, interpretation, display and reporting.

Significant performance characteristics:

- Full 12 lead ECG
- Small, low weight (<300 g)
- Data transfer by blue-tooth
- Single AA battery operation
- Pacemaker detection with 4000 Hz sample rate
- 500 Hz per channel transmission rate
- Bandwidth: 0.05-150 Hz
- Resolution: < 2.5 μ V/bit
- Classification applied parts; CF, defibrillator proof
- Automatic analysis by HES stress/resting algorithm package
- Online evaluation and display of HR, ST-values and ST-slope
- Arrhythmia detection
- Different views
 - Rhythm view
 - Trace view
 - Full disclosure view (result view)
- Different filters selectable
 - 50/60 Hz
 - Baseline
 - Muscle (20, 40, 100 Hz)
- Continuous storage of raw ECG data for stress application

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). 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.

5.13 Required Components

- PC or Notebook with Bluetooth interface
- SentrySuite Software
- Vyntus ECG amplifier
- Bag for the Vyntus ECG amplifier
- Instruction for Use
- NiMH battery charger
- Accessories
 - Disposable electrodes (Rest)
 - Disposable electrodes (Stress)
 - NiMH rechargeable battery 1,2V AA \geq 2500 mAh

5.14 Summary Table of Comparison

| Comparison with MasterScope ECG K082539 | | |
|--|---|--|
| | MasterSope ECG (K082539) | Vyntus ECG (proposed device) |
| indication for Use | <p>The MasterScope / MasterScope ECG is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow volume measurements. Mostly it will be used for COPD and Asthma patients. In addition it is intended for measuring a 3/6- or 12-channel surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-channel ECG's are analysed automatically and suggestions for the interpretation of the 12-channel ECG can be made by the software.</p> <p>MasterScope / MasterScope ECG can be used for non interpretive applications for patients with an age of 4 years and older and a weight of 20 kg or higher.</p> <p>MasterScope / MasterScope ECG is intended for use in routine ECG recording by trained physicians in the office or hospital. MasterScope / MasterScope ECG is</p> | <p>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.</p> <p>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</p> |

| | | |
|--|---|---|
| | <p>not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients.</p> <p>MasterScope CT (Clinical Trial version) incorporates the identical measurements. In addition it offers workflow control elements to restrict the use of the equipment (e.g. individual access rights are defined for different user roles like investigator, doctor, study nurse, trainer and service personnel).</p> <p>The interpretation software is intended to support the physician in evaluation the ECG in terms of morphology and rhythm.</p> <p>A qualified physician has to reassess all MasterScope / MasterScope ECG measurements. An interpretation by MasterScope / MasterScope ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the MasterScope / MasterScope ECG 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.</p> <p>The MasterScope / MasterScope ECG / MasterScope CT is powered from 100 - 240V / 50 - 60Hz wall outlets. No energy is transferred to the patient.</p> | <p>findings.</p> <p>Additional for Vyntus ECG:</p> <p>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.</p> <p>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.</p> |
| intended Use | 12-channel Surface ECG recording device | similar |
| target population | 4 years and older and a weight of 20 kg or higher | similar |
| application | ECG recording | similar |
| bandwidth | 0 – 150 Hz digital | similar |
| ECG Leads | 12 Standard | similar |
| A/D resolution | 2,6 µV/bit | similar |
| pacemaker detection sample rate | 4000 Hz | similar |
| connection to electrodes | 4 mm snap connector, gold plated | similar |
| electrode impedance | Impedance measurement for the electrode | similar |
| patient contacting accessory (biocompatibility) | <ul style="list-style-type: none"> • Single use electrode (Ambu Blue Sensor) • Electrode cable | similar |
| material ECG amplifier | ABS/PC (no patient contacting part) | ABS/PC white RAL 9003 (no patient contacting part) |

| | | |
|--|--|--|
| enclosure | | |
| sterility | The device along with its accessories is neither supplied sterile nor intended to be sterilized | Similar |
| Evaluation algorithm | Hannover ECG System (HES) | Similar |
| Interpretation algorithm (resting ECG) | Hannover ECG System (HES) | Similar |
| Comparison with Vyntus / SentrySuite Product Line K133925 | | |
| | Vyntus / SentrySuite Product Line (K133925) | Vyntus ECG (proposed device) |
| Software | <ul style="list-style-type: none"> • Software platform SentrySuite • SentrySuite Software version 2.11 | <ul style="list-style-type: none"> • Software platform SentrySuite • SentrySuite Software version 2.13 |
| Comparison with Cor12+ K091505 | | |
| | Cor12+ (K091505) | Vyntus ECG (proposed device) |
| Interface | Bluetooth & SD card | Bluetooth |
| energy used | 2 x 1,5V (AA size, Lithium) | 1,5V AA battery or 1,2V AA NiMH rechargeable battery |

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

- The ECG part of the indications for use for the predicate MasterScope ECG and the indication for use of the Vyntus ECG are similar. Both devices record ECG's for the similar patient population.
- The material from the housing in both devices is PC-ABS. Different is that the housing of the Vyntus ECG is in addition with the colour additive white RAL 9003.
- The software platform used for the Vyntus ECG is similar to the predicate device Vyntus / SentrySuite Product line K133925. The software which is used is the SentrySuite software but here with a different version.
- The interface communication of the Vyntus ECG and the predicate Cor12+ is realized over Bluetooth connection. Different is that the Vyntus ECG uses Bluetooth connection only whereby the Cor12+ can also be used with a SD card for data transfer. Both devices work as intended and the proposed device is substantial equivalent to the predicate.
- The energy source of the Vyntus ECG is similar to the predicate Cor12+. Both devices use a battery whereby the Vyntus ECG can be used with a rechargeable battery too.

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 & IEC 60601-2-25 | 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 10993-1 | The proposed device passes the applicable tests and standards |

Summary Discussion of Bench Performance Data

The CareFusion Vyntus ECG passed all specified test requirements. The validation and verification testing confirmed this device meets user needs and design inputs for an electrocardiograph 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 and biocompatibility. 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 Carefusion Vyntus ECG meets the functional claims and intended use as described in the product labeling. The Vynuts ECG is substantially equivalent to the predicate devices described in the submission.

5.16 Conclusion

Based on the above, CareFusion concludes that the Vyntus ECG is substantially equivalent to the legally marketed predicate devices and as safe as effective as the predicates.