DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 16, 2016

Carefusion Germany 234 Gmbh
Elmar Niedermeyer
Regulatory Affairs
Leibnizstrasse 7
D-97204 Hoechberg
Germany

Re: K153654
Trade/Device Name: Sentry Web SmartInterp
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, BZC
Dated: August 12, 2016
Received: August 15, 2016

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153654

Device Name
Sentry WEB SmartInterp

Indications for Use *(Describe)*

Sentry WEB SmartInterp is a medical software which is intended to be used as an aid in the evaluation and diagnosis of already measured cardiopulmonary data. Access to data will be realized via network or internet with assigned access rights. Patient population is not assigned as it is defined by the measuring devices itself.

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: 15/12/2015

5.2 Submitter

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Programmable Diagnostic Computer
(CFR 870.1425, Product Code DQK)
Pulmonary function data calculator
(CFR 868.1880, Product Code BZC)

5.5 Trade Name

Sentry WEB SmartInterp

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

74 Cardiovascular Part 870 (Primary)
Code DQK
73 Anesthesiology Part 868 (Secondary)
Code BZC

5.8 Reason for Premarket Notification

- New device (evaluation software)

5.9 Legally predicate marketed device

- SentrySuite Product Line K122699 Code BTY, BZG, BZC, JEH
  (CareFusion Germany 234 GmbH)
- Vyntus/SentrySuite Product line K150810 Code BZC, DPS
  (CareFusion Germany 234 GmbH)
- RespiEvents software K012020 Code DQK
  (Non-Invasive Monitoring Systems Inc.)

5.10 Device Description

Sentry Web SmartInterp is a web application providing support for execution of post-measurement related clinical tasks like re-evaluation, quality grading and interpretation of medical readings.
Sentry WEB SmartInterp does not primarily rely on electronic document formats – PDF-like reports – but utilizes modern web technologies to create a rich web-based user experience.
Due to its general approach Sentry WEB SmartInterp can serve in many environments as ‘the post-measurement’ solution – customer-owned or as cloud based software service. Hence, Sentry WEB SmartInterp on one hand

extends stand-alone diagnostic systems by running on the measurement system as local post-measurement component. For small labs Sentry WEB SmartInterp enables the attending physician to supervise several measurement units from his office. In mid-sized cardiopulmonary labs Sentry WEB SmartInterp introduces optimized post-measurement workflow capabilities. Finally in sophisticated multi-site setups Sentry WEB SmartInterp supports the channeling of data and creates the throughput required for large clinical teams.

5.11 Intended Use Statement

Sentry WEB SmartInterp is a medical software which is intended to be used as an aid in the evaluation and diagnosis of already measured cardiopulmonary data. Access to data will be realized via network or internet with assigned access rights. Patient population is not assigned as it is defined by the measuring devices itself.

5.12 Required Components

- Workstation / Server / Notebook / Tablet
- Sentry WEB SmartInterp software
- Instruction for Use

5.13 Summary Table of Comparison

Comparison to predicate devices SentrySuite Product Line K122699 & Vyntus/SentrySuite Product Line K150810			
	SentrySuite Product Line K122699	**Vyntus/SentrySuite Product Line K150810**	**Sentry WEB SmartInterp (new device)**
Indication for Use	The SentrySuite Product line 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 on-line 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. Use of the Option Bronchial Challenge requires the supervision of a physician familiar with emergency medicine. 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.	The Vyntus/SentrySuite product line is intended to be used for measurements, data collection and analysis of lung function (PFT) and cardio-pulmonary (CPET) parameters, aiding in the diagnosis of related conditions. The results of the test can be viewed online with the help of a computer screen and can be printed after the test. The test results can be saved for future reference or report generation purposes. The products can be utilized with patients age 4 years and older as long as they can cooperate in the performance - no special limit to patient's sex or height exists. Measurements will be performed under the direction of a physician in a hospital environment, physician's office or similar setting (professional healthcare facilities). A qualified physician has to reassess all Vyntus/SentrySuite measurements. An interpretation by Vyntus/SentrySuite is only significant if it is considered in connection with other clinical findings. **Additional for Vyntus ECG:** The Vyntus ECG is intended for measuring the surface electro-cardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-lead ECGs are analyzed automati-cally and suggestions for the interpretation of the resting ECG can be made by the soft-ware. 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 measure-ment 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.	Sentry WEB SmartInterp is a medical software which is intended to be used as an aid in the evaluation and diagnosis of already measured cardiopulmonary data. Access to data will be realized via network or internet with assigned access rights. Patient population is not assigned as it is defined by the measuring devices itself. **Rationale** There is no significant difference in indication for use for evaluation and diagnosis of patient data from pulmonary function and cardio pulmonary exercise testing. The evaluation and diagnosis module of SentrySuite and Sentry WEB SmartInterp is similar and thereby the proposed device is substantial equivalent to the predicate device.
Patient population	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.	4 years and older and a weight of 20 kg or higher	**similar** **Rationale** The patient population

			will be defined by the measuring device itself. As the patient population depends on the measuring device, the Sentry WEB SmartInterp patient population is identical to the predicate SentrySuite devices. There is no difference and that is why the proposed device is substantial equivalent to the predicates.
Software	SentrySuite	SentrySuite	Sentry WEB SmartInterp (evaluation part of SentrySuite) **Rationale** The Sentry WEB SmartInterp software is as stand-alone version of the evaluation and diagnosis module of the predicate SentrySuite devices. There is no new option or feature in Sentry WEB SmartInterp which is not available in the predicate SentrySuite devices. Thereby the proposed device is substantial equivalent to the predicate devices.
Performance (display of measurements)	• Spirometry • Flow / Volume • MVV • R-Oclusion (Airway Resistance) • FRC Helium Rebreathing • Real Time Single Breath Diffusion • Intra Breath Diffusion • Single Breath Diffusion CO/He • Bodyplethysmography • Respiratory Drive P0.1 • PI/PE Max (MIP/MEP) • Impulse oscillometry • Bronchial test o Bronchospasm lysis o Broncho provocation o Pulsed Nebulization o Continuous Nebulization	• Spirometry • Flow / Volume • MVV	**similar** (to K122699 & K150810) **Rationale** The evaluation and diagnosis module of Sentry WEB and SentrySuite is exact the same. That means, that only parameters can be evaluated which are already available in the predicate SentrySuite devices. There is no possibility to evaluate any new parameters as the evaluation modules are identical. Thereby the proposed device is substantial equivalent to the predicate devices.

		• Breath-by-Breath • Indirect Calorimetry • Stress & Resting ECG	**similar** (to K150810)

Comparison to predicate device RespiEvents Software K012020

	RespiEvents Software K012020	**Sentry WEB SmartInterp (new device)**
Software characteristics	• Displays recorded signals from measuring device • Logging already measured values • Aid in identifying and classifying measured data • Provides analysis of already captured data • Evaluating measured physiological data	**Similar** **Rationale** The Both software can display signals from measuring devices, logging already measured values, add in identifying and classifying measured data, provide analysis of captured data and evaluate measured physiological data. Thereby the proposed software is substantial equivalent to the predicate software.
Intended use	Software running on a computer intended for analyzing and displaying of already measured data	**Similar** **Rationale** Both medical software are for running on a computer intended for analyzing and displaying of already measured data. Thereby the proposed software is substantial equivalent to the predicate software.

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

- The Indication for Use for Sentry WEB SmartInterp is similar to the predicate devices. It is for evaluating and diagnosis of Cardio Pulmonary data. The SentrySuite software package consists of all these possibilities.
- The patient population for the SentrySuite is similar to the patient population of Sentry WEB SmartInterp as the patient population of Sentry WEB SmartInterp depends on the SentrySuite measuring device.
- The Sentry WEB SmartInterp software is similar to the SentrySuite evaluation and diagnosis module as all the Sentry WEB SmartInterp options are available in the predicate SentrySuite software.
- The displayed measurement parameters which can be evaluated are all present in the predicate devices under the software SentrySuite.
- The software Characteristics of Sentry WEB SmartInterp and the predicate RespiEvents software are similar.
- The intended use of Sentry WEB SmartInterp and the predicate RespiEvents is similar.

5.14 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. Accuracy Testing	Accuracy of evaluated Data	The proposed device passes the applicable tests and standards
Summary Discussion of Bench Performance Data		
The CareFusion Sentry WEB SmartInterp passed all specified test requirements. The validation and verification testing confirmed this device meets user needs and design inputs for PFT and CPET. Testing also confirmed physical attributes and device performance meet the requirements of the standards listed in the performance testing summary above. These standards address risk management, usability and software life cycle. 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 Sentry WEB SmartInterp meets the functional claims and intended use as described in the product labeling. The Sentry WEB SmartInterp is substantially equivalent to the predicate device described in the submission.

5.15 Conclusion

Based on the modifications above, CareFusion concludes that the Sentry WEB SmartInterp software is substantially equivalent to the legally marketed predicate software devices and as safe as effective as the predicates.