510(k) Summary K122699

NOV 19 2012

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 08/16/2012

5.2 Submitter

Name: CareFusion Germany 234 GmbH

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Germany

Contact person in Germany:

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Calculator, Predicted Values, Pulmonary Function
(CFR 868.1890, Product Code BTY)
Pulmonary function data calculator
(CFR 868.1880, Product Code BZC)
Diagnostic Spirometer
(CFR 868.1840, Product Code BZG)
Volume plethysmograph
(CFR 868.1760, Product Code JEH)

5.5 Trade Name

SentrySuite Product Line

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868
Code BTY, BZG, BZC, JEH

5.8 Reason for Premarket Notification

--- Modification of legally marketed devices ---
Change from previously **JLAB** software to **SentrySuite** software for some measurement programs of the device MasterScreen PFT Body K072061

5.9 Legally predicate marketed device

SentrySuite Product Line	K111053 Code BTY, BZC, BZG
MasterScreen PFT Body	K072061 Code JEH
MasterScreen Body / Diff	K936108 Code JEH

5.10 Predicate Device Company

CareFusion Germany 234 GmbH

5.11 Device Description

The SentrySuite Product line when operating on the existing hardware for MasterScreen Pneumo, MasterScreen IOS, APS Pro and MasterScreen PFT will be as functional as the existing version of JLAB software for all the available measuring programs and options for these devices.

- The SentrySuite software replaces the JLAB software and got a brand-new graphical surface.
- Measurement can be accomplished under SentrySuite software equivalent as it was possible under the previously powerful JLAB software

- The results of the tests can be viewed on-line on the computer screen during the test and can be saved on the computer hard disk for further referral or report generation purposes.
- SentrySuite provides the functionality currently available on the MasterScreen devices using the JLAB software.
- SentrySuite can be operated on workstations and on servers.

Measurements:

- Spiormetry
- Flow Volume
- Maximal Voluntary Ventilation (MVV)
- Incentive Spirometry
- R-Occlusion
- Impulse oscillometry
- Bronchial test
- FRC Helium Rebreathing
- Real Time Single Breath Diffusion
- Intra Breath Diffusion
- Bodyplethysmography
- Respiratory Drive P0.1
- PI/PE Max (MIP/MEP)
- Single Breath Diffusion CO/He

5.12 Intended Use Statement

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.

5.13 Required Components

- Measuring device MS-Pneumo or MS-IOS or APS Pro or MS-PFT or MS-PFT Body or MS Body Diff
- Or Workstation / Server
- Trolley / Stand
- High performance computer

- Printer
- Accessories
- SentrySuite software 2.7x
- Instruction for Use

5.14 Summary Table of Comparison

A) Comparison to predicate device SentrySuite Product Line K113813		
	SentrySuite Product Line (K113813)	**SentrySuite Product Line**
Indications 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.	**identical**
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.	**Identical**
Hardware	**APS Pro** • Nebulizer head • Compressor • Trolley or Stand with power supply • Desktop / Notebook • Accessories **MasterScreen Pneumo** • Trolley or Stand with power supply • Pneumotach handle • Desktop / Notebook • Accessories	**identical**

	MasterScreen IOS • Trolley or Stand with power supply • Pneumotach handle • Desktop / Notebook • Accessories **MasterScreen PFT / PFT Body** • Trolley with power supply • Analyzer box (gas) • Pneumotach handle • Body Box • Desktop / Notebook • Accessories	
Software	SentrySuite Software (version 2.5)	SentrySuite Software (version 2.7x)
Performance specification (measurement programs)	**APS Pro** • Bronchial test o Bronchospasmolysis o Bronchoprovocation o Pulsed Nebulization o Continuous Nebulization **MasterScreen Pneumo** • Spirometry • Incentive Spirometry • Flow / Volume • MVV • R-Occlusion (Airway Resistance) **MasterScreen IOS** • Spirometry • Incentive Spirometry • Flow / Volume • MVV • Impulse oscillometry **MasterScreen PFT / PFT Body** • Spirometry • Incentive Spirometry • Flow / Volume • MVV • R-Occlusion (Airway Resistance) • FRC Helium Rebreathing • Real Time Single Breath Diffusion • Intra Breath Diffusion	**identical**
Energy type	100 – 240V / 50 – 60Hz	**identical**
Patient contacting parts	• Single Use mouthpiece (material: Bormed RG835 MO) • Silicone mouthpiece • Nose clip (material: Polyacetal) • Nose clip pad (material: Ethylene Vinyl	**identical**

	Acetate)	
Sterili-zation	The devices from the SentrySuite Product Line (APS Pro, MS Pneumo, MS IOS, MS PFT) along with its accessories are neither supplied sterile nor intended to be sterilized	**identical**
Software Network options	• Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Data integration • Database handling • JINET server	**Identical**

B) Comparision to predicate device MasterScreen PFT K072061		
	MasterScreen PFT (K072061)	**SentrySuite Product Line**
Perfor-mance specifica-tion (measure-ment programs)	**MasterScreen PFT** • Spirometry • Incentive Spirometry • Flow / Volume • MVV • R-Occlusion (Airway Resistance) • FRC Helium Rebreathing • Real Time Single Breath Diffusion • Intra Breath Diffusion • **Diffusion Single Breath CO/He** • **Bodyplethysmography** • **Respiratory Drive P0.1** • **PI/PE Max (MIP/MEP)**	**Identical**
Hardware	**MasterScreen PFT** • Trolley with power supply • Analyzer box (gas) • Pneumotach handle • Body Box • Desktop / Notebook • Accessories	**Identical**
Software	**MasterScreen PFT** JLAB Software 5.x	SentrySuite Software (version 2.7x)

C) Comparison to predicate device MasterScreen Body Diff K936108		
	MasterScreen Body Diff (K936108)	**SentrySuite Product Line**
Perfor-mance specifica-tion (measure-ment programs)	**MasterScreen Body / Body Diff** • Spirometry • Incentive Spirometry • Flow / Volume • MVV • R-Occlusion (Airway Resistance) • Bodyplethysmography • Respiratory Drive P0.1 • PI/PE Max (MIP/MEP) • Single Breath Diffusion CO/He	**Identical**
Hardware	**MasterScreen Body / Body Diff** • Trolley with power supply • Pneumotach handle • Body Box (with or without Analyzer box) • Desktop / Notebook • Accessories	**Identical**
Software	**MasterScreen Body / Body Diff** JLAB Software 5.x	SentrySuite Software (version 2.7x)

Discussion to the two tables above:

The insignificant difference from the SentrySuite Product Line with 510(k) K113813 to the extended SentrySuite Product Line is:

- The SentrySuite software with version 2.5 will be superseded by the SentrySuite software with version 2.7. The existing measurement programs for the medical applications for APS Pro, MasterScreen Pneumo, MasterScreen IOS and MasterScreen PFT remain thereby untouched.
- The measurements in bold printed characters of MasterScreen PFT K072061 of table "B" above will be added to the SentrySuite Product Line with the SentrySuite software version 2.7.

In Summary: The SentrySuite Product Line K113813 with software SentrySuite 2.5 will be expanded with the measurements "Diffusion Single Breath CO/He, bodyplethysmograpy, respiratory drive P0.1 and PI/PE Max (MIP/MEP)" and the software version will be the SentrySuite 2.7.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the SentrySuite Product Line:

- The modification for the above device was developed in accordance with the CareFusion Design and Development SWI (0301-5001-000-SWI).
- The risk analysis method used to assess the impact of the SentrySuite software was a Failure Modes and Effects Analysis (FMEA) according standard ISO 14971.

Summary detail of the non-clinical performance testing for the following measurement programs:

- Diffusion Single Breath CO/He
- Bodyplethysmography
- Respiratory Drive P0.1
- PI/PE Max (MIP/MEP)

Human subjects were tested on the above devices with the predicate JLAB software and also with the new SentrySuite software 2.7.
The results obtained with the predicate software JLAB and with the SentrySuite 2.7 software were compared statistically. The bivariate correlation test was chosen to compare the measurements. Beside the correlation coefficient also the one-tail p-value for the test pairs for each selected parameter was calculated. The one-tail p-values were used, as only positive correlation coefficients are judged significant and a requirement for "pass". The pass/fail criterion was defined based on a significant level of 0.01 for the p-value.

Results of compared key parameters:

➢ Diffusion Single Breath CO/He (DLCO, VA, Vin)	p-value <0,0001 / pass
➢ Bodyplethysmography (TLC, FRCpl, RV, sReff, Reff)	p-value <0,0001 / pass
➢ Respiratory Drive (P0.1)	p-value <0,0001 / pass
➢ PI/PE Max (MIP/MEP)	p-value ≤0,0004 / pass

The comparison of the measured values of the subjects shows statistically significant correlation between the new SentrySuite 2.7 software and the predicate software JLAB. The pass criterion was fulfilled by all measurements and parameters.
This performance testing demonstrates that the subject device is as safe and effective as the predicate device and meets the intended uses.

5.16 Conclusions

Based on the above, CareFusion Germany 234 GmbH concludes that the SentrySuite Product Line with the SentrySuite software is substantially equivalent to the legally marketed predicate devices and is safe and effective for its intended use, and performs at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 19, 2012

Mr. Elmar Niedermeyer
Regulatory Affairs Specialist
CareFusion Germany 234 GmbH
Leibnizstrasse 7
Hoechberg
Bavaria, Germany 97204

Re: K122699
Trade/Device Name: SentrySuite Product Line
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BTY, BZG, BZC, JEH
Dated: August 24, 2012
Received: September 4, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402

Anthony D. Watson, B.S., M.S., M.B.A.
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): K122699

Device Name: SentrySuite Product Line

Indications 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 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.
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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.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2012.11.19 13:57:15 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122699