

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 28/03/2011

5.2 Submitter

Name: CareFusion Germany 234 GmbH

Address: Leibnizstrasse 7
D-97204 Hoechberg
Germany

Contact person in Germany:

(Regulatory Affairs Specialist)

Address:

Elmar Niedermeyer

CareFusion Germany 234 GmbH
Leibnizstrasse 7, 97204 Hoechberg
Germany

Phone:

+49 931 49 72 - 361

FAX:

+49 931 49 72 - 62361

E-mail

elmar.niedermeyer@carefusion.com

Contact person in the U.S.:

(Official Correspondent)

Address

Carol Emerson

CareFusion
22745 Savi Ranch Parkway
Yorba Linda, CA 92887

Phone:

714-919-3342

Fax:

714-283-8420

E-mail:

carol.emerson@carefusion.com

5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

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

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

5.8 Reason for Premarket Notification

--- Modification of legally marketed devices ---
Change from previously **JLAB** software to **SentrySuite** software for the
devices MasterScreen Pneumo, MasterScreen IOS, APS Pro

5.9 Legally predicate marketed device

MasterScreen Pneumo	K071753 Code BTY
MasterScreen IOS	K954140 Code BZG
APS Pro	K001502 Code BZC

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 and APS Pro 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

5 510(k) Summary

- 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:

- Spirometry
- Flow Volume
- Maximal Voluntary Ventilation (MVV)
- Incentive Spirometry
- R-Occlusion
- Impulse oscillometry
- Bronchial test

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 Workstation / Server
- Trolley / Stand
- High performance computer
- Printer
- Accessories
- SentrySuite software
- Instruction for Use

5.14 Summary Table of Comparison

Comparison with the predicate devices

	MasterScreen IOS (K954140)	MasterScreen Pneumo (K071753)	APS Pro (K001502)	SentrySuite Product line
Indications for Use	<p>The MasterScreen IOS is intended to be used for measurement and data collection of lung function parameters in humans. The system performs cooperation-dependent pulmonary function tests which include Spirometry/Flow-Volume/Resistance measurements and the IOS (multifrequent oscillometry determination) measurement. Tests can be easily and quickly conducted on the basis of Impulse Oscillometry. The device is useful in the field of early diagnosis in every-day-routine, for clinical trend observations as well as for epidemiologic studies. As only a minimum of patient cooperation is required, Impulse Oscillometry is also suitable for pediatric and geriatric studies. Measurements will be performed under the direction of a physician in the clinic, doctor's office or hospital.</p> <p>The MasterScreen IOS is powered from 100-240 V / 50-60 Hz wall outlets. No energy is transferred to the patient.</p>	<p>The Masterscreen Pneumo 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. Measurements will be performed under the direction of a physician in the clinic, doctor's office or hospital. It can be utilized for patients from 4 years on and older as long as they can cooperate in the performance.</p> <p>The Masterscreen Pneumo is powered from 100-240V / 50-60Hz wall outlets. No energy is transferred to the patient.</p>	<p><u>General</u> The Aerosol Provocation System (APSpro) is intended for specific and non-specific bronchial hyperreactivity tests (provocation tests), as well as for reversibility tests using bronchodilators. The system is to be used together with a PC-based lung-function equipment of Jaeger together with a Jaeger compressor to measure and to display simultaneously the results during a patient reaction. For the D.S. market only legally marketed nebulizers which are also approved by Jaeger are allowed to be used with the APS-pro. Currently only the SIDESTREAM nebulizer manufactured by Medic-Aid Ltd. is approved (K924123).</p> <p><u>Place of use</u> The system is only to be used in-door. The required ambient conditions are</p> <ul style="list-style-type: none"> • Temperature: +10 to +40°C • Relative humidity: 30% to 75% • Barometric pressure: 700 to 1060 mBar <p><u>Patient groups</u> The system is to be used for testing patients from 4 years upwards. Tests with the APSpro are to be performed by the order of a physician only. During the tests trained personal must be available.</p>	<p>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.</p>
Patient population	<p>MasterScreen IOS can be used for pediatric and geriatric studies.</p>	<p>It can be utilized for patients from 4 years on and older as long as they can cooperate in the performance.</p>	<p>The system is to be used for testing patients from 4 years upwards.</p>	<p>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.</p>

5 510(k) Summary

Hardware	<ul style="list-style-type: none"> • IOS head • Trolley or Stand with power supply • Pneumotach handle • Desktop / Notebook • Accessories 	<ul style="list-style-type: none"> • Trolley or Stand with power supply • Pneumotach handle • Desktop / Notebook • Accessories 	<ul style="list-style-type: none"> • Nubulizer head • Compressor • Trolley or Stand with power supply • Desktop / Notebook • Accessories 	identical
Software	JLAB Software	JLAB Software	JLAB Software	SentrySuite Software
Performance specification (measurement programs)	<ul style="list-style-type: none"> • Impulse oscillometry • Spirometry • Flow / Volume • Maximal Voluntary Ventilation (MVV) • Incentive Spirometry 	<ul style="list-style-type: none"> • R-Occlusion • Spirometry • Flow / Volume • Maximal Voluntary Ventilation (MVV) • Incentive Spirometry 	<ul style="list-style-type: none"> • Bronchial test <ul style="list-style-type: none"> ○ Bronchospasmodolysis ○ Bronchoprovocation ○ Pulsed Nebulization ○ Continuous Nebulization 	identical
Energy type	100 – 240V / 50 – 60Hz	100 – 240V / 50 – 60Hz	100 – 240V / 50 – 60Hz	identical
Patient contacting parts	<ul style="list-style-type: none"> • Single Use mouthpiece (material: Bormed RG835 MO) • Silicone mouthpiece • Nose clip (material: Polyacetal) • Nose clip pad (material: Ethylene Vinyl Acetate) 	<ul style="list-style-type: none"> • Single Use mouthpiece (material: Bormed RG835 MO) • Silicone mouthpiece • Nose clip (material: Polyacetal) • Nose clip pad (material: Ethylene Vinyl Acetate) 	<ul style="list-style-type: none"> • Single Use mouthpiece (material: Bormed RG835 MO) • Silicone mouthpiece • Nose clip (material: Polyacetal) • Nose clip pad (material: Ethylene Vinyl Acetate) 	identical
Sterilization	The MasterScreen IOS along with its accessories is neither supplied sterile nor intended to be sterilized	The MasterScreen Pneumo along with its accessories is neither supplied sterile nor intended to be sterilized	The APS Pro along with its accessories is neither supplied sterile nor intended to be sterilized	identical
Software Network options	<ul style="list-style-type: none"> • Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Data integration • Database handling • JINET server 	<ul style="list-style-type: none"> • Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Data integration • Database handling • JINET server 	<ul style="list-style-type: none"> • Use as Workstation • Use as Server • Online connection • Vlink connection • GDT connection • Data integration • Database handling • JINET server 	Identical

Discussion to the table above:

The insignificant difference from the SentrySuite Product line to the devices MasterScreen-~~IOS K954140~~, MasterScreen-Pneumo-K071753 and-APS Pro K001502 is:

- **The JLAB software will be superseded by the new SentrySuite software. The measurement programs for the medical applications for each device remain the same.**

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 software was developed according to IEC 62304 (Software life-cycle processes) and IEC 62366 (Usability) standard.
- The risk analysis method used to assess the impact of the new software SentrySuite was a Failure Modes and Effects Analysis (FMEA) according standard ISO 14971.

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.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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

AUG 12 2011

Re: K111053
Trade/Device Name: SentrySuite Product Line
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: BTY, BZC, BZG
Dated: July 28, 2011
Received: August 1, 2011

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.

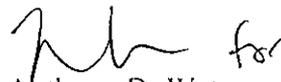
Page 2 – Mr. Niedermeyer

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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111053

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.

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Magdalena for L. Scholtzeis
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111053

Page 1 of _____