K101573

FEB 10 2011

510(k) Summary

GENERAL INFORMATION

5.1 Type of Submission

Special 510(k) Submission

Submission date: 22/06/2010

5.2 Submitter

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Diagnostic Spirometer (CFR 868.1840, Product Code BZG)

5.5 Trade Name

MasterScreen IOS

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868
Code BZG

5.8 Reason for Premarket Notification

Device modification to an existing CareFusion – device regarding "The New 510(k) Paradigm"
-- change from 16 bit software to 32 bit software --

5.9 Legally predicate marketed device

MasterSreen IOS
K954140/A001 Code BZG

5.10 Predicate Device Company

CareFusion Germany 234 GmbH

5.11 Device Description

MasterScreen IOS is a diagnostically medical device for lung function testing for the early detection of pathological changes and their onset in the small airways and provides the following advantages:

- Quick and low-cost noninvasive determination of Respiratory Impedance with low technical expenditure
- Differentiation between proximal (central airways) and distal (peripheral airways) pulmonary components
- Sensitive detection and differentiation of extrathoracic changes in the respiratory system
- Save method for differentiation between trapped air or respiratory collapse and obstruction
- Recorded parameters provide valuable information for early diagnosis of pulmonary diseases
- Graphic interpretation of the results on the basis of a simple lung-thorax model
- Airway impedance via complete VC-maneuver allows to answer further clinical questions

- Differentiated determination of bronchial hyper reactivity of both provocation and spasmolysis independent of cooperation.
- Determination of static (VC_{in}, VC_{ex}, ...) and dynamic (FVC, FEV_1, FEF_{50}, ...) lung volumes by the proven Spirometry/Flow-Volume program.

Measurements:

- Impulse oscillometry
- Spirometry
- Flow / Volume
- Maximal Voluntary Ventilation (MVV)

5.12 Intended Use Statement

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.

The MasterScreen IOS is powered from 100-240 V / 50-60 Hz wall outlets. No energy is transferred to the patient.

5.13 Required Components

- IOS measuring unit including impulse generator, flow and pressure sensor
- Trolley / Stand
- High performance personal computer / Notebook
- Printer
- Acquisition interface
- Acquisition software
- Accessories
- Instruction for Use

5.14 Summary Table of Comparison

	MasterScreen IOS (K954140)	**MasterScreen IOS** with 32 bit software
Indications for Use	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. The MasterScreen IOS is powered from 100-240 V / 50-60 Hz wall outlets. No energy is transferred to the patient.	**identical**
Patient population	MasterScreen IOS can be used for pediatric and geriatric studies.	**identical**
Hardware	• IOS head • Trolley or Stand with power supply • Pneumotach handle • Desktop / Notebook • Accessories	**identical**
Software	JLAB 4.x 16 bit version	JLAB 5.x 32 bit version
Performance specification (measurement programs)	• Impulse scillometry • Spirometry • Flow / Volume • Maximal Voluntary Ventilation (MVV)	**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 Acetate)	**identical**
Sterilization	The MasterScreen IOS along with its accessories is neither supplied sterile nor intended to be sterilized	**identical**
Fundamental scientific Technology	multifrequent oscillometry technique (IOS head) / pressure to flow conversion technique (pneumotach handle)	**identical**

Discussion to the table above:

The insignificant difference to the MasterScreen IOS K954140/A001 is:

- **The JLAB Software changes from 16 bit version to 32 bit version**

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the MasterScreen IOS with 32 bit JLAB software:

- The modification for the above device was developed in accordance with the Cardinal Health development standard operating procedures (000490 09 – Design Control).
- The software was developed according to IEC 62304 (Software life-cycle processes) and IEC 60601-1-6 (Usability) standard.
- The risk analysis method used to assess the impact of MasterScreen IOS with 32 bit software was a Failure Modes and Effects Analysis (FMEA).

5.16 Conclusions

Based on the above, CareFusion Germany 234 GmbH concludes that the MasterScreen IOS with the 32 bit JLAB software is substantially equivalent to legally marketed predicate device and is safe and effective for its intended use, and performs at least as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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GERMANY

FEB 10 2011

Re: K101873
Trade/Device Name: MasterScreen IOS
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: February 2, 2011
Received: February 7, 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.

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,

for

Anthony 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): K

Device Name: MasterScreen IOS

Indications for Use:

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.

The MasterScreen IOS is powered from 100-240 V / 50-60 Hz wall outlets. No energy is transferred to the patient.

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)

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

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