K100925

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MAR - 7 2011

510(k) Summary

Device Name: Diagnostic Spirometer
Device Trade Name: Micro Diary Spirometer
Common/Classification Name: Diagnostic Spirometer

Contact Person and Submitter:
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Substantial Equivalence
The Micro Diary Spirometer is substantially equivalent to the previous version of the Micro Diary Spirometer (K965042).

Description of the device
The Micro Diary Spirometer is a compact, hand held, and battery operated recording spirometer. The device features a five button keypad and an LCD display. The device utilizes a digital volume transducer. As a patient's exhaled breath is passed through the transducer, the vane rotates. The number of rotations is proportional to the volume of air passed through the transducer, and the frequency of rotation is proportional to the flow rate.

Indications for Use Statement
The Micro Diary Spirometer is used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs. Specifically, the Micro Diary Spirometer measures the following lung function parameters: FEV1, FVC, FEV6 and PEF.

Target Population
The device can be used on patients who require lung function measurements. These patients are usually suffering from diseases such as asthma and chronic obstructive pulmonary disorder. It can be utilized for patients from 4 years and older, providing that they are able to follow the medical practitioner's instructions.

Environment of Use
The environment of use is the hospital or a doctor's or medical practitioner's office or clinic or the patient's home.

Technological Characteristics

The updated version of the Micro Diary Spirometer has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device, which is previous version of the Micro Diary Spirometer (K965042).

Comparison of Technological Characteristics

As a result of tooling and component obsolescence, it was necessary to produce a direct replacement for the previous version of the Micro Diary Spirometer using current tooling and available components. Both devices perform standard spirometric measurements, and both are capable of recording the test results for review at a later time. The MicroDiary (new) and the older MicroDiary perform exactly the same functions and tests.

	Micro Diary (new)	Micro Diary (previous)
Parent Company	CareFusion	CareFusion(Formerly Cardinal Health, Viasys, Micro Medical
Device Classification name	Diagnostic Spirometer	Diagnostic Spirometer
510(k) Number	New	K965042
Indications for Use	Measures lung function as follows: FEV1, FVC, FEV6, and PEF.	Measures lung function as follows: FEV1, FVC, FEV6, PEF
Display Screen	LCD Display, B&W	LCD Display, B&W
User interface	5 Keys – on, up, down, enter, and delete	5 Keys – on, up, down, enter, and delete
Measurement Transducer	Turbine	Turbine
Power supply	Battery	Battery

Nonclinical Testing

The Micro Diary Spirometer was tested to assure that it accurately measures lung function across the following standard spirometric measures: FEV1, FVC, FEV6, and PEF. All tests were passed successfully. Electrical Safety and Electromagnetic Compatibility testing was also performed and passed.

Clinical Testing

No clinical testing was submitted for device.

Conclusion

The testing has demonstrated that the device is as safe, as effective, and performs as well as or better than the legally marketed Micro Diary Spirometer (K965042).

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

Mr. Merritt Girgis
Manager, Regulatory Affairs
CareFusion
22745 Savi Ranch Parkway
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MAR - 7 2011

Re: K100928
Trade/Device Name: Micro Diary Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: March 2, 2011
Received: March 3, 2011

Dear Mr. Girgis:

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,

Anthony D. Watson

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
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Center for Devices and
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Enclosure

EXHIBIT A
Statement of Indications for Use

510(k) Number (if known): Not known.

Device Name: Micro Diary Spirometer

Indications for Use: The Micro Diary Spirometer measures lung function using the following standard spirometric measures: FEV1, FVC, FEV6, and PEF. The device also records the test data for later review and has the ability to transfer these test records to a compatible computer.

Target Population: Patients requiring lung function measurements.

Environment of Use: Under the supervision of a medical practitioner.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

510(k) Number: K100928

Statement of Indications for Use

510(k) Number: K100928.

Device Name: Micro Diary Spirometer

Indications for Use: The Micro Diary Spirometer is used in pulmonary function testing to measure the volume of gas moving in or out of a patient's lungs. Specifically, the Micro Diary Spirometer measures the following lung function parameters: FEV1, FVC, FEV6 and PEF.

Target Population: The device can be used on patients who require lung function measurements. These patients are usually suffering from diseases such as asthma and chronic obstructive pulmonary disorder. It can be utilized for patients from 4 years and older, providing that they are able to follow the medical practitioner's instructions.

Environment of Use: The environment of use is the hospital or a doctor's or medical practitioner's office or clinic or the patient's home.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K100928