APR 13 2012

CareFusion

510(k) Summary

k 113096

GENERAL INFORMATION

5.1 Type of Submission

Traditional 510(k) Submission

Submission date: 10/10/2011

5.2 Submitter

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Spirometer, Diagnostic
(CFR 868.1840, Product Code BZG)

5.5 Trade Name

Micro I

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

--- new device ---

5.9 Legally predicate marketed devices

- Microlab Spirometer K031102 Code BZG
- Micro Diary K100928 Code BZG

5.10 Predicate Device Company

CareFusion

5.11 Device Description

Description & function:

The Micro I spirometer is a hand held portable microprocessor based device designed to measure expiratory flows and volumes.
To perform a spirometry test the user first inserts a mouthpiece into the mouthpiece holder of the spirometer, which aligns it with the volume transducer. The unit is then turned on and displays instructions and prompts according to the device type. When prompted to do so by the operator, the patient inhales as deeply as possible, seals his/her lips around the mouthpiece and exhales as hard and as fast as possible until no more air can be exhaled. The device converts the airflow to an electrical signal, and the onboard software calculates the required values.

Scientific Concept:

The scientific concept which forms the basis of this device is the Carefusion uni-directional digital volume transducer. The transducer consists of an acrylic tube with a freely rotating vane supported on jewelled bearings positioned between a fixed swirl plate and a cross bar. As air is passed through the transducer, a vortex is created by the

swirl plate, which causes the low inertia vane to rotate. The rotation of the vane is detected by the interruption of an infra red beam which produces an electrical pulse train at the output of a phototransistor. The number of rotations is proportional to the volume of air passed through the turbine, and the rate of rotation is proportional to the flow rate. Using the integrated software the Micro I calculates a range of expiratory indices.

Significant physical & performance characteristics:

Performance (measurements)

Forced Expired Volume in 1 second	(FEV1)
Forced Expired Volume in 6 second	(FEV6)
Forced Vital Capacity	(FVC)
Forced Expiratory Ratio	(FEV1/FEV6)
Forced Expiratory Ratio	(FEV1/FVC)
Peak Expiratory Flow Rate	(PEF)
Mid Expiratory Flow	(FEF25-75)
Expiratory Flow at 75% of volume remaining	(FEF75)
Expiratory Flow at 25% of volume remaining	(FEF75)

Dimensions

162 x 61 x 30mm

Weight

152g

Display

128 x 128 pixel graphic backlit monochrome LDC

Transducer type

CareFusion Uni-Directional Digital Volume

Power supply

2 x AA size NiMH rechargeable cells

5.12 Intended Use Statement

The Micro I spirometer is intended to measure the maximal volume and flow of air that can be moved out of a patient's lungs. The system is intended for use with pediatric and adult patients over the age of 3 years in hospitals, physician offices, laboratories and occupational health testing environments.

5.13 Required Components

- Micro I spirometer
- Digital Volume Transducer
- Cardboard Mouthpieces
- USB/Charging cable
- Cardboard Mouthpiece Adapter
- Instruction for Use
- PSU
- Accessories

5.14 Summary Table of Comparison

	MicroLab K031102	Micro Diary K100928	Micro I K113096 (new)
Indications for Use	The Microlab spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.	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.	The Micro I spirometer is intended to measure the maximal volume and flow of air that can be moved out of a patient's lungs. The system is intended for use with pediatric and adult patients over the age of 3 years in hospitals, physician offices, laboratories and occupational health testing environments.
Target population	Pediatric (4 to 17 years) Adult (18 to 99 years)	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 pulmo-nary disorder. It can be utilized for patients from 4 years and older, providing that they are able to follow the medical practitioner's instructions.	Over the age of 3 years
Perfor-mance specifica-tion (measure-ment para-meter)	VC, FEV75, FEV1, FEV3, FEV6, FVC, PEF, FEV75/VC, FEV75/FVC, FEV1/VC, FEV1/FVC, FEV3/VC, FEV3/FVC, FEV75/FEV6, FEV1/FEV6, FEF75, FEF50, FEF25, FEF25-75, FEF50/VC, FEF50/FVC, MVV, FIV1, FIVC, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, FEF50/FIF50, MET2575, FET, TV, ERV, IRV, IC, EVC, IVC, FR, Ti, Te, Ti/Ttot, TV/TI	FEV1, FVC, FEV6, PEF	FEV1, FVC, FEV6, FEV1/FVC, FEV1/FEV6, PEF, FEF25, FEF75, FEF25-75
Transducer material (breathing path contacting)	Turbine swirl plate (Polycarbonate) Turbine van (Polyester type 427) Turbine tube (Clear Acrylic) Pivot (Nivapoint stainless steel)	Turbine swirl plate (Makrolon 2607) Turbine van (Polyester type 427) Turbine tube (Makrolon 2607) Pivot (Nivapoint stainless steel)	**Identical** (to K100928)
	Turbine Flow deflector (stainless steel) Mouthpiece holder (ABS Plastic)	N/A	Turbine Flow deflector (stainless steel) Mouthpiece holder (PC/ABS Cycoloy C2800)
Transducer (type)	Type 36-TDX 1048 CareFusion Bi-Directional Digital Volume	Type 36-TDX 1050 CareFusion Uni-Directional Digital Volume	Type 36-TDX 1051 CareFusion Uni-Directional Digital Volume
Resolution	0,01 liter	0,01 liter	**Identical** (to K100928 & K031102)

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	MicroLab K031102	Micro Diary K100928	Micro I K113096 (new)
Accuracy (FEV1/FVC/ PEF)	+/- 3% to ATS Recommendations	to the requirements of the ATS/ERS Taskforce: Standardization of Spirometry 2005	**Identical** (to K100928)
Volume Range	0.1 – 8 Litres	0 – 8 l as per ATS/ERS	**Identical** (to K100928)
Flow Range	0.2 – 15 Litres/Second	0.2 – 15 Litres/Second	0 – 14 l as per ATS/ERS
Sterilization	Turbine can be sterilized or cleaned	Turbine can be sterilized or cleaned	**Identical** (to K100928 & K031102)
User input type	Touchscreen (PC/ABS)	Keypad 5 key (Silicon rubber)	Keypad 4 key (Silicon rubber)
Anatomical sites (Housing)	255 x 120 x 35 mm Weight: 630g Handle (transducer): 50 x 60 x 90	130 x 57 x 37 mm Weight: 100g	162 x 61 x 30 mm Weight: 152g
Housing material (patient contacting)	PC/ABS Cycoloy C2950 (Housing) Polyurethane "rubber feel" & black ABS (Transducer)	PC/ABS Babyblend T65 (Housing)	PC/ABS Cycoloy C2800 (upper & lower casing & MLD1621 Mouthpiece adaptor) PC/ABS LEXAN 141 Resin (case tube) Alexit 401-75 soft coating (coating for upper & lower case)
Display	Colour 1/4 VGA LCD	Graphic LCD monochrome size 44,0 x 27,0 100 x 64 dot matrix	Graphic LCD monochrome size 33,90 x 33,90 128 x 128 dot matrix
Display & keypad foil material (patient contacting)	PC/ABS (Cycoloy C 2950) no patient contact	Clarex Precision Optical Sheet (Cast Acrylic sheet)	**Identical** (to K100928)
Energy used (battery)	8,4V NiMH 1000mAh	3V Lithium Coin Cell (CR2450), 600mAh	2.4V NiMH AA, 1600mAh
Environ-mental specifi-cations	Operating: 0 to +40 °C 30% to 90% RH Storage: -20 to +70 °C 10% to 90% RH	Operating: 0 to +40 °C 30% to 90% RH Storage: -20 to +70 °C 10% to 90% RH	Operating: 10 to +35 °C 20% to 80% RH Storage: -20 to +70 °C 30% to 90% RH

	MicroLab K031102	Micro Diary K100928	Micro I K113096 (new)
Accessory (patient contacting)	VOL2104 Nose Clips (pack of 5) Body material: Polyacetal Pad material: Ethylene Vinyl Acetate	VOL2104 Nose Clips (pack of 5) Body material: Polyacetal Pad material: Ethylene Vinyl Acetate	**Identical** (to K100928 & K031102)
	PSA1000 Adult Disposable Mouthpiece (material: Polyethylene coated bleached kraft paper) SST1250 One-way Safety Mouthpiece (250 per box) (material: Polyethylene coated bleached kraft paper / Safety wheel & valve: Polystyrene & Rectaleen 8/170) SST1000 One-way Safety Mouthpiece (500 per box) (material: Polyethylene coated bleached kraft paper / Safety wheel & valve: Polystyrene & Rectaleen 8/170) PSA1200 Paediatric Disposable Mouthpiece (material: Polyethylene coated bleached kraft paper)	PSA2200 Mouthpiece (material: ABS)	**Identical** (to K031102 & also used in Micro Diary Card K965042)
	PSA1100 Paediatric adapter (Polypropylene co-polymer, natural Stamylan P512MN10, colour UN0001 white)	N/A	**Identical** (to K031102)

Summary to the table above:
The Micro I and the main predicate device MicroLab have the same indication for use only the sentence for the patient population has been changed into "over the age of 3 years" instead of "4 years to 17 years" and "18 to 99 years". The Micro I has the same technological characteristics as the predicate devices. For the materials used in the Micro I spirometer which are not identical to the predicate devices a biocompatibility test has been done. The patient contacting accessories are the same as used in the predicate devices.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the Micro I Spirometer:

- The modification for the above device was developed in accordance with the CareFusion Design and Development QP 0301.
- The modifications were developed according to IEC 62366 (Usability) standard.

- The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA) according standard ISO 14971.
- Biocompatibility for the patient contacting material has been tested according ISO 10993-1 standard at Nelson test laboratory in the USA.
- Safety and EMC testing to IEC 60601-1 and IEC 60601-2
- Packaging test
- Environmental Testing (climatic chamber)
- Testing according ATS/ERS standardization of lung function testing

5.16 Conclusion

Based on the above, CareFusion 232 UK concludes that the Micro I Spirometer is substantially equivalent to the legally marketed predicate devices, the CareFusion Microlab Spirometer K031102 and Micro Diary K100928 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Elmar Niedermeyer
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GERMANY 97204

APR 13 2012

Re: K113096
Trade/Device Name: Micro I
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: February 27, 2012
Received: February 29, 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,

for

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): K113096

Device Name: Micro I

Indications for Use:

The Micro I spirometer is intended to measure the maximal volume and flow of air that can be moved out of a patient's lungs. The system is intended for use with pediatric and adult patients over the age of 3 years in hospitals, physician offices, laboratories and occupational health testing environments.

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)

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

510(k) Number: K113096