K103515 NOV - 9 2011

510(k) Summary

Sponsor:	PMD Healthcare
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Telephone:	484-664-7600
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Contact Person:	Wayne Meng
Summary Preparation Date:	November 7, 2011
Device Name:	
Trade Name:	SPIRO PD
Common/Usual Name:	Spirometer
Classification Name:	Spirometer, Diagnostic
Regulation Number:	868.1840
Product Code:	BZG
Device Class:	Class 2
Review Panel:	Anesthesiology

Predicate Device

Company Name	Product Name	510(k) Number
SDI Diagnostics	Spirotel	K031643
Vitalograph	Model 4000 Series	K073155

Device Description

The **SPIRO PD** spirometer is an instrument that acquires mechanical signals and processes the information provided by the signal related to the pulmonary function. For processing purposes, mechanical signals must be changed to electrical signals. The devices responsible for this change are called transducers. The **SPIRO PD** has a Turbine-type transducer. The turbine transducer performs transduction in two stages: The volume to be measured crosses the turbine vane and records its rotation that is proportional to that Volume, this rotation is detected by the interrupting of a beam of infrared light, the sensor of which converts the light received into a digital-type electrical signal.

The **SPIRO PD** performs the following tests:

- FVC,
- FEV1
- FEV1/FVC
- PEF
- FEF 25-75%
- Estimated Lung Age and Flow/Volume Curve

The **Spiro PD** performs the following calculations:

- % Predicted of FVC
- Severity of FVC
- % Predicted of FEV1
- Severity of FEV1
- % Predicted of FEV1/FVC
- Severity of FEV1/FVC
- % Predicted of FEF 25-75%
- Severity of FEF 25-75%
- % Predicted of PEF, Severity of PEF

The physical configuration of the Spiro PD:

- Display – Color, Touch screen LCD 320 x 240 resolution
- Keyboard – Touch screen
- Power supply – 3.7V Lithium-ion battery 650 mAh
- Dimensions – 200 x 96 x 40mm
- Weight – 256g with battery

Device Indications for Use

The SPIRO PD spirometer is intended to be used by a patient under the instruction of a physician or respiratory therapist to test lung function in child, adolescent and adult. It is also intended to be used as a single-patient device only and can be used in the home, factory, hospital or physician's office.

The Spiro PD spirometer is indicated for the following age groups:

- 2-12 years - Child
- 13-21 years - Adolescent
- 22 and over- Adult

Predicate Product Comparison

12.2 Predicate Product Comparison Chart

Predicate Product Comparison Chart			
Parameter	SPIRO PD	SDI Diagnostics' Spirotel	Vitalograph
510(k) Number		K031643	K073155
Indications for Use (IFU)	Indications For Use: The SPIRO PD spirometer is intended to be used by a patient under the instruction of a physician or respiratory therapist to test lung function in people of all ages. It is also intended to be used as a single-patient device only and can be used in the home, factory, hospital or physician's office. The Spiro PD spirometer is indicated for the following age groups: • 2-12 years - Child • 13-21 years - Adolescent • 22 and over- Adult	Indications For Use: The Spirotel spirometer is intended to be used by a patient under the instruction of a physician or respiratory therapist to test lung function in people of all ages. It is also intended to be used as a single-patient device only and can be used in any setting - home, factory, hospital or physician's office.	The Vitalograph Model 4000 is a battery powered, handheld electronic spirometer used to measure Peak Flow (PEF) and Forced expired volume (FEV).
Device Description	The SPIRO PD spirometer is a hand-held portable diagnostic spirometer for the measurement of patient breath flow	The Spirotel Spirometer is a hand-held portable diagnostic spirometer for the measurement of patient breath flow	The Vitalograph Model 4000 series {ama-1 and copd-6} are battery powered handheld electronic spirometers used to

	and volume. The device uses a turbine transducer that measures flow via infrared interruption. Algorithms are used to determine values based on this flow measurement. Tabular and graphical data are displayed on the spirometer LCD display.	and volume. The device uses a turbine transducer that measures flow via infrared interruption. Algorithms are used to determine values based on this flow measurement. Tabular and graphical data are displayed on the spirometer LCD display	measure expired Peak Flow and Forced Expired Volume after one second. The results can aid in the diagnosis of Asthma and COPD in patients. All variants {asma-1 and copd-6} within the range use the very same operating principle, LCD, Buttons, and Mouldings. Items that may vary within the range are list of parameters that the different variants display. I.e., Asma-1 displays FEV1 and PEF whilst the copd-6 displays FEV1 and FEV6 only. A uni-directional rotating vane with flow sensor to measure lung function is used. The measurements are taken via expiration into the unit flowhead, which is in-turn displayed onto and LCD.
Physical Configuration	Display: Color, Touchscreen LCD 320 x 240 resolution Keyboard:	Display: STN LCD, 2 lines x 16 alphanumeric characters Keyboard:	Display: Color LCD Keyboard;

	Touchscreen Power supply: 3.7V Lithium-ion battery 650 mAh Dimensions: 200 x 96 x 40mm Weight: 256g with battery	5 keys membrane Power supply: 3V Lithium battery CR123A Dimensions: 70 x 80 x 30mm Weight: 100g with battery	User Buttons Power Supply: 2 x 1.5v AAA batteries Dimensions 113 x 63 x 48mm Weight: 83g with battery
Power Source	3.7 V, 650 mAh Lithium-ion Battery	3V Lithium Battery	2x1.5v AAA Battery
ATS Spirometry Performance Recommendations	Yes	Yes	Yes
Cross Contamination Control	Yes, single patient device.	Yes	Yes
Flow Detection Principle	Digital Turbine	Digital Turbine	Rotor Stator Design
Flowmeter Calibration Method	Factory Calibration	Factory Calibration	Factory Calibration
Display and Printer Used	The SPIRO PD uses a color touchscreen LCD	STN LCD, 2 Lines x 16 alphanumeric characters	The Vitalograph Model 4000 uses a color LCD Display
Graphic Output	Graphic output can be shown on the LCD screen and downloaded to a computer	Graphic output can be shown on the LCD screen and downloaded to a computer	Graphic Output shown on LCD screen and downloaded to a computer
Tests Performed	FVC, FEV1, FEV1/FVC, PEF, FEF 25-75%, Estimated Lung Age and Flow/Volume Curve	FVC, FEV1, FEV1%, PEF, FEF25-75%, FET, and Flow/Volume Curve	FEV_1, FEV_6, FEV_1/FEV_6 and estimated Lung Age
Indices Calculated	% Predicted of FVC, Severity of FVC, % Predicted of FEV1, Severity of FEV1, % Predicted of FEV1/FVC, Severity of FEV1/FVC, % Predicted of FEF 25-	% Predicted of FVC, Severity of FVC, % Predicted of FEV1, Severity of FEV1, % Predicted of FEV1/FVC, Severity of FEV1/FVC, % Predicted of FEF 25-	FEV1 and FEV1 % Predicted FEV6 and FEV6 % Predicted FEV1/FEV6 and FEV1/FEV6 Predicted FEV1/FVC ration

	75%, Severity of FEF 25-75%, % Predicted of PEF, Severity of PEF	75%, Severity of FEF 25-75%, % Predicted of PEF, Severity of PEF	
Predictive Models Used	NHANES III	NHANES III, Crapo, Morris	NHANES III
General Electrical Safety Tests IEC 60601-1 and IEC 60601-1-2	Yes	Yes	Yes
Provides Test date and time, plus symptom scores	Yes	Yes	Yes
Diary storage	180 days	100 Days	None
Replies to simple questions and test quality control	Yes	Yes	No
Maximum Volume	0 – 10 L	10 L	0.9.99 L BTPS
Flow Range	0 -16 L/s	+16 L/s	0.15 kPa/L/s at 14 L/s
Flow Accuracy	±5% or 200 mL/s	±5% or 200 mL/s	±3%
Volume Accuracy	±3% or 50 mL, whichever is greater	±3% or 50 mL, whichever is greater	±3%
Lung Age	Yes	NO	Yes
Test Duration	Minimum of three tests at 15 sec per test.	60 sec	
Technical Specifications	Temperature range: 15 ºC – 50 ºC Humidity Range: Relative humidity below 95% (without condensation) Atmospheric Pressure Range: 430mmHg to 800 mmHg	Temperature range: 15 ºC – 50 ºC Humidity Range: Relative humidity below 95% (without condensation) Atmospheric Pressure Range: 430mmHg to 800 mmHg	Temperature Range: 17-37°C Humidity Range: 10-95% Relative Humidity

Summary of Biocompatibility Tests

Standard	Test Description	Results
ISO 10993-5	Elution Test (ISO)	The test article's extracts meet the requirements of the test.
ISO 10993-10	Guinea Pig Closed Patch Sensitization Test (ISO) Cottonseed Oil Extract	This test article's cottonseed oil extract elicited a minimal sensitization reaction in guinea pigs under the conditions of this test.
ISO 10993-10	Guinea Pig Closed Patch Sensitization Test (SO) Saline Extract	This test article's saline extract did not elicit a sensitization reaction in guinea pigs under the conditions of this test.
ISO 10993-10	Primary Dermal Irritation in Rabbits (ISO) Cottonseed Oil Extract	This test article's cottonseed oil extract elicited a negligible dermal response in rabbits under the conditions of this test.
ISO 10993-10	Primary Dermal Irritation in Rabbits (ISO) Saline Extract	This test article's saline extract elicited a negligible dermal response in rabbits under the conditions of this test.

Electrical Testing Summary

Table 3 Electrical Safety and EMC Tests and Results

Standard	Description of Test	Results
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
IEC 60601-1-4	Medical electrical equipment Part 1-4 – Collateral Standard: Programmable electrical medical systems	Pass
IEC 60601-1-6	Medical electrical equipment Part 1-6 – Collateral Standard: Usability	Pass
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Pass

Human Factor Study

PMD Healthcare conducted a Human Factor Study using 45 participants.

- 15 Participants 2-12 years of age
- 15 Participants 13-21 years of age
- 15 Participants 22+ years

Summary of Results

Ease of Use scores for all age groups averaged greater than 92.5%
Label comprehension scores for all age groups averaged 97%

Comparison of Spiro PD to Predicate Devices

Indications for Use

The Indications for Use of Spiro PD are identical to the Spirotel device with the addition of a clarification of the age groups of the intended users.

Technological Characteristics

The Spiro PD and the predicate devices are physically & technologically similar. All devices are portable, hand-held, battery powered devices for measurement of lung performance. The Spiro PD and Spirotel utilize lithium-based batteries while the Vitalograph uses AAA batteries. All3 devices are similar in size and weight.

All 3 devices adhere to the American Thoracic Society (ATS) guidelines. The Spiro PD is a single patient device; the mouthpiece is removable and can be cleaned. The Spirotel has a disposable mouthpiece. Both the Spiro PD and the Spirotel device employ digital turbine technology to measure flow. All 3 devices are calibrated at the factory.

All 3 devices employ an LCD to present information; the Spirotel is not color. All 3 devices can download to a computer. The Spiro PD and the Spirotel devices measure the most commonly used lung performance parameters and calculate the most common indices. All 3 devices use the NHANES III equations for their predictive models.

All 3 devices meet the safety requirements for medical electrical equipment.

All 3 devices provide the test date and time, plus symptom scores for each test. Both the Spiro PD and the Spirotel save a large number of test data sets. The maximum volume, flow range, flow accuracy, and volume accuracy are the same for the Spiro PD and the Spirotel; the Vitalograph has minor differences.

Both the Spiro PD and the Vitalograph devices estimates lung age; the Spirotel does not. The Vitalograph Model 4000 device is included as a Predicate Device specifically because it estimates lung age as does the Spiro PD.

The Spiro PD and Vitalograph have minimum test durations of 15 seconds per test and a minimum of 3 tests per session per the ATS guidelines. The Spirotel test duration has a maximum of 60 seconds.

All 3 devices operate in the same range of temperature, humidity, and pressure. The Vitalograph does not specify an operating range for atmospheric pressure.

The differences between the Spiro PD and the predicate devices are minor. The Spiro PD has a touch screen user interface while the Spirotel has a 5 key membrane and the Vitalograph has user buttons. All 3 means allow the user to enter information similarly.

Spirotel & Vitalograph use batteries that are not rechargeable whereas the Spiro PD can be recharged. This does not create a meaningful difference in the way in which the devices operate.

The Vitalograph device uses a rotor stator design to measure flow rather than digital turbine technology. Both methods provide sufficient accuracy.

The Vitalograph only measures FEV1, FEV6, FEV1/FEV6 and Lung Age and calculates the associated indices. Although the Vitalograph does not measure the full range of parameters as the Spiro PD and Spirotel, it is measures a subset of these parameters including lung age.

The Spirotel can use the Crapo equations in addition to the NHANES III for its predictive model. Although this provides an alternative model, the NHANES III method is employed by the Spiro PD and both predicate devices.

The differences in the technological characteristics between the Spiro PD and the predicate devices are minimal. All 3 devices are portable, hand-held, battery powered devices for measurement of lung performance. They employ similar means of user interaction, data presentation, and measure the same parameters adhering to the ATS guidelines.

Non-clinical data

The Spiro PD has passed all electrical safety and EMC tests that are required for medical devices. It has passed the standard tests required by IEC 60601-1, IEC 60601-1-4, IEC 60601-1-6, IEC 60601-1-6, IEC 60601-1-2.

The patient contacting materials of the Spiro PD have passed biocompatibility testing in accordance with ISO-10993.

Human Factors/Usability testing was carried out across all 3 age groups to evaluate use related risks and labeling comprehension. The data generated in this study provided confidence that all the 3 age groups were able to use the device and to achieve the expected results in accordance with the intended use.

Clinical data

Clinical data was not required to determine the safety and effectiveness of the Spiro PD or to show substantial equivalence to the predicate devices. Therefore, no clinical data was collected or assessed as part of this 510(k) premarket notification.

Conclusion

Based on a comparison of the Spiro PD and the predicate devices with regard to their intended use and their technological characteristics, and based on successful completion of all device testing and thorough evaluation of use-related risks assessed during human factor studies, PMD healthcare concludes that the Spiro PD is safe and effective, and is substantially equivalent to legally marketed 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

PMD Healthcare
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Crofton, Maryland 21114

NOV - 9 2011

Re: K 103575
Trade/Device Name: SPIRO PD
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: November 7, 2011
Received: November 7, 2011

Dear Mr. Smith:

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 Form

Indications for Use

510(k) Number (if known):

Device Name: SPIRO PD

Indications for Use:

The SPIRO PD spirometer is intended to be used by a patient under the instruction of a physician or respiratory therapist to test lung function in child, adolescent and adult. It is also intended to be used as a single-patient device only and can be used in the home, factory, hospital or physician's office.

The SPIRO PD spirometer is indicated for the following age groups:

- 2-12 years - Child
- 13-21 years - Adolescent
- 22 and over- Adult

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schulthess

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

510(k) Number: K103575