

K092324

510(k) Summary

SEP - 8 2009

GENERAL INFORMATION

5.1 Type of Submission

Special 510(k) Submission

Submission date: 07/17/2009

5.2 Submitter

Name: Cardinal Health Germany 234 GmbH

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Oxymeter (CFR 870.2700, Product Code DQA)
Predicted pulmonary-function value calculator
(CFR 868.1890, Product Code BTY)

5.5 Trade Name

SpiroPro

5.6 Device Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology
Part 870 Code DQA and Part 868 Code BTY

5.8 Reason for Premarket Notification

Device modification to an existing Cardinal Health – device regarding
"The New 510(k) Paradigm"
-- Additional data transfer to computer by blue tooth --

5.9 Legally predicate marketed device

- SpiroPro SpO2
K031515 / Code DQA, BTY
- AM1+ / AM1+ BT
K090486 / Code BZG

5.10 Predicate Device Company

Cardinal Health Germany 234 GmbH

5.11 Device Description

SpiroPro® is a recording and diagnostic system for measurement, recording and assessment of the Flow-Volume curve and Flow-Volume parameters. The analyzed data can be immediately printed out or saved to the internal memory.

The portable spirometer is small, easy to handle and allows determination of inspiratory and expiratory lung volumes (VCin, FVC, FEV1, MEF50, ...) including pre and post measurement with date and time display. An interpretation program automatically assesses the measured data. Optionally, the measurement of the oxygen saturation of the blood (SpO2) and the pulse rate are available and a 6-minute walk test can be performed.

The graphic LCD and the menu-guided graphical user interface comply with the latest technological developments. Just touch the appropriate icon with your finger to enter patient data or to select menu items (touch screen). Self-explanatory icons and the logical menu structure safely guide you through the procedure. Storage capacity is high: up to 550 measurements can be saved in the internal database.

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The rechargeable lithium-ion battery allows operation of the SpiroPro® for approximately two weeks. A charging unit, able to charge the battery within two hours, is included in the delivery.

Patient data, recording results and graphs can be directly printed out on a PCL-compatible printer (for example HP DeskJet series). Of course, data transfer to a PC and vice versa is possible via the serial interface and the Bluetooth interface. The optional software package "SpiroPro® for Windows®" allows automatic transfer of data which are then saved on the PC.

The easy-to-exchange, high-quality pneumotach guarantees a high degree of patient safety and provides precise recording results.

5.12 Intended Use Statement

The SpiroPro is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home. The SpiroPro measures inspiratory and expiratory lung function parameters in adults and children 4 years and older. In addition to the pulmonary function measurements, oxygen saturation and heart rate can be recorded.

5.13 Required Components

- SpiroPro (with Nonin Xpod Patient Cable Oximeter)
- Nonin Finger Clip Sensor
- Pneumotachograph set
- Plastic Disposable Mouthpiece
- Nose clip
- Lithium-ion battery 3,7V, rechargeable
- Charging unit
- Printer cable
- Printer adapter
- User Manual
- SpiroPro for Windows Software (option)

5.14 Summary Table of Comparison

a) Comparison with SpiroPro SpO2 with 510(k) K031515

	SpiroPro SpO2 (K031515)	SpiroPro with Bluetooth
Indications for Use	The SpiroPro is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home. The SpiroPro measures inspiratory and expiratory lung function parameters in adults and children 4 years and older. In addition to the pulmonary function measurements, oxygen saturation and heart rate can be recorded.	identical

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Fundamental scientific Technology	<u>Spirometer:</u> Pneumotachograph, pressure to flow conversion technique <u>Oximeter:</u> Conventional dual wavelength pulse technique	identical
Accessories	<ul style="list-style-type: none"> • Pneumotachograph set • Finger clip sensor • Nose clip 	identical
Patient contacting parts	<ul style="list-style-type: none"> • Finger clip sensor • Nose clip pad 	identical
	<ul style="list-style-type: none"> • Single use mouthpiece (material: Hostalen GD 6250) 	Single use mouthpiece (material: Bormed RG835 MO)
Housing material	Rotec ABS 1001FR V0	identical
Pneumotach material	Rotec ABS 1001FR V0	identical
Disinfection	Mouthpiece (single patient use)	identical
	Pneumotach (single patient use)	Identical (but is validated for disinfection)
Display / Key-panel	LCD touch screen 120*64 dots / 3*4 touch	Successor model
Micro-controller	Micro-controller with internal memory	Successor model
Interface	RS232 Interface	identical
Energy type	1 x 3,7V Lithium-ion battery	identical
Off-the-Shelf Software	Option	identical

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ATS conformity (criteria)	ATS 1994	ATS 1994 and ATS-ERS 2005
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Discussion to the table above:

The insignificant differences to the SpiroPro SpO2 are found as:

- **Single use Mouthpiece** – The material for the single use mouthpiece has changed from Hostalen GD 6250 to Bormed GR 835 MO. For the material Bormed GR 835 MO a biocompatibility test according ISO 10993-1 was successful accomplished.
- **Pneumotach** – The pneumotach for the SpiroPro now is reusable and has been validated for disinfection with an FDA approved disinfectant. The high level disinfectant for semi-critical devices “Cidex OPA Solution” with 510(k) K030004 can be used.
- **ATS criteria** – For evaluation of the measurement now the ATS criteria according ATS 2005 can be selected in the setting menu beside the ATS 1994 criteria. This means, the result can also be shown on the screen of the SpiroPro according the ATS 2005 criteria.
- **Micro-controller** – has been replaced by a successor model due to the fact that the previous Micro-controller will be not manufactured anymore. Successor model: Micro-controller MB96 F 346 / 16 bit
- **LCD-Display** - has been replaced by a successor model due to the fact that the previous LCD display will be not manufactured anymore. Successor model: LCD module type – JCG12064A02-02

b) Comparison with AM1+ / AM1+ BT with 510(k) K090486

	AM1+ / AM1+ BT (K090486)	SpiroPro with Bluetooth
Interface	RS232 Interface & Bluetooth	identical

Discussion to the table above:

The similarities to the AM1+ / AM1+ BT are found as:

- **Bluetooth** – is used for data transfer to the computer as an additional possibility besides the serial interface communication. The Bluetooth module for the SpiroPro device is identical to the Bluetooth module in the AM1+ / AM1+ BT. Both devices work with the Bluetooth module Mitsumi WML-C46.

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the SpiroPro with the Bluetooth data transmission:

- The Bluetooth data transmission for the above device was developed in accordance with the Cardinal Health development standard operating procedures (000490 06 – Design Control).
- The risk analysis method used to assess the impact of SpiroPro with the additional Bluetooth data transmission was a Failure Modes and Effects Analysis (FMEA).
- Safety test procedures demonstrate satisfaction of all safety requirements and mitigation of all identified hazards.
- The EMC testing was performed according EN 60601-1-2.

5.16 Conclusions

Based on the above, Cardinal Health Germany 234 GmbH concludes that the SpiroPro is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use, and performs at least as well as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Mr. Thomas Rust
Regulatory Affairs Manager
Viasys Healthcare GmbH
Leibnizstrasse 7,
D-97204 Hoechberg
GERMANY

SEP - 3 2009

Re: K092324
Trade/Device Name: SpiroPro
Regulation Number: 21 CFR 868.1890
Regulation Name: Oximeter
Regulatory Class: II
Product Code: BTY, DQA
Dated: July 30, 2009
Received: August 5, 2009

Dear Mr. Rust:

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.

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*

Susan Runner, D.D.S., M.A.
Acting 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): K092324

Device Name: SpiroPro

Indications for Use:

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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)

L Schulz
(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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