NOV 2 1 2011

MIR
MEDICAL INTERNATIONAL RESEARCH

510(k) Summary K 103530

1. Applicant Information

Date Prepared:	November 09, 2011
Submitter:	MIR Medical International Research
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2. Device Information

Trade Name:	Spirodoc
Classification Name:	spirometer and oximeter

3. Identification of legally marketed device to which the submitter claims equivalence:

Company Name:	MIR
Device Name:	Spirobank II
510(k) number:	K061712

4. Description of the device:

Spirodoc is a pocket-size spirometer and oximeter.

The device is made up of:

- a central unit which measures and collects information related to the state of health of the patient, with wireless or cable transmission of the collected data using a microprocessor based system with a touch screen display, USB communication port and Bluetooth,
- a removable sensor for the measurement of respiratory air flow and volume,
- a removable pulse oximetry sensor

Stored data can be then delivered through landline, broadband, wireless and cell-phone technology to be received by a web server and can then be accessed by medical staff.

5. Statement of Intended Use:

The Spirodoc Spirometer and pulse oximeter is intended to be used by a physician or by a patient under the prescribed use of a physician.

The device is intended to test lung function and can perform spirometry testing in adult and pediatric patients, excluding infants and neonates, and oximetry readings in patients of all ages.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:
Spirodoc uses the same measurement method and sensors, and calculates the same parameters as the predicate device.

It has a new enclosure, whose thickness is half that of the predicate device.
The part accommodating the spirometry sensor (turbine) is now detachable.
It uses a touch-screen display instead of a keyboard.

It uses a new microprocessor (and a new PCB), and the same oximetry board as the predicate device.

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of SE.
Testing was done to ensure that the Spirodoc would perform safely and accurately within the environments for which it is to be marketed.

Safety and environmental testing was conducted in accordance with EN 60601-1:1990 and EN 60601-1-2:1993. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing have been completed. The results demonstrates that the Spirodoc is in compliance with the guideline and standards referenced and that it performs within its specifications.

Testing of device performance included clinical testing of both spirometry and pulse oximetry functions.
Spirometry testing was performed according with American Thoracic Society (ATS) Standards. The results obtained were within the range of accuracy required by ATS.
The accuracy of SpO2 and pulse rate have been verified in-house using an optical simulator. The results obtained were within specification.

8. Conclusions
Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed device.

This summary on 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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. Ed Kohere
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1900 Pewaukee Road, Suite O
Waukesha, Wisconsin 53188

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Re: K103530
Trade/Device Name: Spirodoc
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG, DQA
Dated: November 9, 2011
Received: November 14, 2011

Dear Mr. Kohere:

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: K103530

Device Name: Spirodoc

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

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

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