K052140

MAR 16 2006

[redacted]
MEDICAL INTERNATIONAL RESEARCH

Summary of Safety and Effectiveness

1. Applicant Information

Date Prepared:	August 2, 2005
Submitter:	MIR Medical International Research
Address:	Via del Maggiolino, 125
	00155 Roma – Italy
Contact Person:	Simon Fowler
Phone Number:	+39 06.22.754.777

2. Device Information

Trade Name:	Spirolab, Spirolab II
Classification Name:	spirometer

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

Company Name:	SDI Diagnostics, Inc.
Device Name:	SDI Spirolab II
510(k) number:	K012812
Regulation Number	868.1840

4. Description of the device:

MIR **Spirolab** and **Spirolab II** are instruments for the analysis of respiratory function, which carries out three different spirometric tests, FVC, VC(insp/exp) and MVV, with a calculation of the main spirometric parameters, predicted values and percentage deviations compared to the measured values. Plus Flow/Volume and Volume/time curves and the interpretation of the FVC test following the international spirometry standards (ATS/ERS).

5. Statement of Intended Use:

The **Spirolab** and **Spirolab II** spirometers are intended to be used by either a physician, respiratory therapist or technician to test lung function in people of all ages excluding infants and neonates. They can be used in any setting.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

MIR **Spirolab** and **Spirolab II** have the

- same intended use
- same operating principle
- same algorithms for spirometry parameters calculation

- same physical aspect (keyboard, display, size and weight)

7. Brief discussion of the clinical and non clinical tests relied on for a determination of SE.

Testing was done to ensure that the MIR Spirolab/Spirolab II 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[SM1]. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing have been completed. The results demonstrates that the MIR **Spirolab** and **Spirolab II** are in compliance with the guidelines and standards referenced and that it performs within its specifications.

Spirometry testing was performed according with American Thoracic Society (ATS) Standards. The results obtained were within the range of accuracy required by ATS.

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
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Mr. Simon Fowler
Sales Manager
M.I.R. Medical International Research (MIR)
Via Del Maggiolino, 125
00155 Roma-Italy

Re: K052140
Trade/Device Name: Spirolab, Spirolab II
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: March 2, 2006
Received: March 6, 2006

Dear Mr. Fowler:

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.

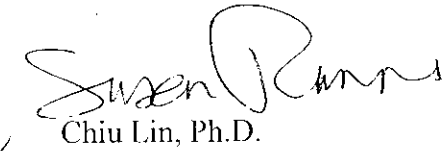
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
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: K052140

Device Name: **Spirolab, Spirolab II**

Indications for Use: The **Spirolab** and **Spirolab II** spirometers are intended to be used by either a physician, respiratory therapist or technician to test lung function in people of all ages excluding infants and neonates. They can be used in any setting.

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)