K082766

MEDICAL INTERNATIONAL RESEARCH

DEC 17 2008

510 (k) Summary

1. Applicant Information

Date Prepared:	June 10, 2008
Submitter:	MIR Medical International Research
Address:	Via del Maggiolino, 125
	00155 Roma – Italy
Contact Person:	Simon Fowler
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2. Device Information

Trade Name:	Minispir - Spirolab III
Classification Name:	spirometer

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

Company Name:	MIR Medical International Research
Device Name:	MIR Spirolab II
510(k) number:	K052140

As Spirometer :
Regulation Number 868.1840

As oximeter:
Regulation Number 870.2700

4. Description of the device:

MIR **Minispir - Spirolab III** 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). What is more **Minispir - Spirolab III** with their integrated oximetry option, can calculate both Oxygen Saturation (expressed as %SpO2) and Pulse Rate (expressed as Beats Per Minutes- BPM). In additon **Minispir - Spirolab III** calculate several (up to 20) additional statistical parameters derived from the SpO2 and the pulse rate.

5. Statement of Intended Use:

The **Minispir - Spirolab III** spirometers and pulse oximeters are intended to be used by either a physician, respiratory therapist or technician.
The devices are intended to test lung function and can make:

- spirometry testing in people of all ages, excluding infants and neonates.
- oximetry testing in people of all ages.

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:

Spirometry function (for both **Minispir** and **Spirolab III**)

The MIR **Spirolab III** has the

- same intended use
- same operating principle
- same spirometry parameters
- same algorithms for spirometry parameters calculation
- same physical aspect (keyboard, display, size and weight)
- same printer

as the **Spirolab II.**

The main differences between **Spirolab III** and **Spirolab II** are shortly described as follow:

- **Spirolab III** has an integrated oximetric option, so it can calculate both Oxygen Saturation (expressed as %SpO2) and Pulse Rate (expressed as Beats Per Minutes-BPM).
- **Spirolab III** has an additional function key to address directly the operator to the oximetric functions.
- The Software of both spirometers use the same algorithms for spirometric values calculations, but the language is different.
- The flow sensor of both **Spirolab III** and **Spirolab II** is outside the device. The flow sensor of **Spirolab III** is **Minispir** . However the **Minispir**'s sensor and turbine are the same as those used in the cleared **Spirolab II**.

MIR **Minispir** has the

- same intended use
- same operating principle
- same spirometry parameters
- same algorithms for spirometry parameters calculation
- same turbine
- same sensor and mouthpiece holders

as the **Spirolab II.**

Minispir has different size, weight and physical aspect from the cleared **Spirolab II.** In fact **Minispir** doesn't have any keyboard and display and it is connected to a PC to show the calculated spirometric results.

Oximetry function (for both **Minispir** and **Spirolab III**)

The MIR **Minispir - Spirolab III** have the same pulse oximetry function as the cleared **MIR Spirotel.**

The MIR **Minispir - Spirolab III** have the

- same intended use
- same operating principle
- same sensors
- same oximetry board
- same oximetry parameters (SpO2, pulse rate)
- same algorithms for oximetry parameters calculation

as the MIR **Spirotel**.
Minispir - Spirolab III calculates more oximetry parameters than **Spirotel**

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 **Minispir – Spirolab III** 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 MIR **Minispir – Spirolab III** are in compliance with the guidelines and standards referenced and that they performs within their specifications.

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 and the statistical parameters which the devices calculate, 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 devices.

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

Mr. Simon Fowler
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Via Del Maggiolino, 125
Roma
ITALY 00155

DEC 17 2008

Re: K082766
Trade/Device Name: Minispir – Spirolab III
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG, DQA
Dated: November 4, 2008
Received: November 17, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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 (if known):

Device Name: **Minispir -Spirolab III**

Indications for Use: The MIR **Minispir – Spirolab III** spirometers and pulse oximeters are intended to be used by either a physician, respiratory therapist or technician.
The devices are intended to test lung function and can make:

- spirometry testing in people of all ages, excluding infants and neonates.
- oximetry testing in people of all ages.

They can be used in any setting.

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

510(k) Number: K082766