JUL 19 2005

K043528

MIR
MEDICAL INTERNATIONAL RESEARCH

# Summary of Safety and Effectiveness

**1. Applicant Information**

| | |
|---|---|
| Date Prepared: | July 8, 2004 |
| 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**

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|---|---|
| Trade Name: | Spirotel |
| Classification Name: | spirometer and oximeter |

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

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| Company Name: | SDI Diagnostics, Inc. |
| Device Name: | Spirotel, Model 29-1020. |
| 510(k) number: | K031643 |

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| Company Name: | BCI, Inc. |
| Device Name: | 3420 "Digit" Pulse Oximeter. |
| 510(k) number: | K013171 |

**4. Description of the device:**

MIR Spirotel is a simple to operate precise pocket spirometer and pulse oximeter (weight only 100g). It measures the most important functional respiratory parameters and monitors the oxygen saturation and pulse rate.

**5. Statement of Intended Use:**

The Spirotel spirometer and pulse oximeter is intended to be used by a physician or by a patient under the instruction of a physician or paramedic to test lung function in people of all ages. It is also intended to be used as a single-patient device and can be used in any setting – home, factory, pharmacy, hospital or physician's office.

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

MIR Spirotel combines in a single device the functions of a spirometer and a pulse oximeter. It is derived from the SDI Diagnostics Spirotel, to which the pulse oximetry function has been

added, through an OEM Oximeter Board, which uses the same technology found in the legally marketed BCI 3420 "Digit" Pulse Oximeter.

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

Testing was done to ensure that the MIR Spirotel 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 Spirotel 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.
For oximetry testing a desaturation trial was conducted. 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

JUL 19 2005

Mr. Simon Fowler
Sales Manger
Medical International, Research SRL (MIR)
Via Del Maggiolino 125
Roma,
ITALY 00155

Re: K043528
Trade/Device Name: SPIROTEL
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG, DQA
Dated: June 30, 2005
Received: July 5, 2005

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,

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: Spirotel

Indications for Use: The Spirotel spirometer and pulse oximeter is intended to be used by a physician or by a patient under the instruction of a physician or paramedic to test lung function in people of all ages. It is also intended to be used as a single-patient device and can be used in any setting – home, factory, pharmacy, hospital or physician's office.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K043528