K081033

MEDICAL INTERNATIONAL RESEARCH

JAN 15 2009

510(k) Summary

1. Applicant Information

Date Prepared:	January 25, 2007
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:	MIROxi
Classification Name:	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:

MIROxi is a pulse oximeter, designed for use by specialist who require a simple, portable and compact device, yet at the same time being capable of calculating more than 30 statistical parameters derived from the SpO2 and pulse rate.

Its connectivity capability (USB, Bluetooth, internal modem for acoustic coupling to telephone, RS232) makes it suitable also for telemedicine applications.

5. Statement of Intended Use:

The MIROxi pulse oximeter is intended to be used by a physician or by a patient under the instruction of a physician or paramedic. The device is intended to test oximetry in people of all ages.

It can be used in any setting

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

MIROxi is directly derived from the Spirobank II. Whereas Spirobank II performs both spirometry and oximetry, MIROxi performs only oximetry testing.

MIROxi uses the same oximetry board and oximetry sensors as the predicate device, and it also calculates the same statistical parameters (derived from the SpO2 and pulse rate).

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

Testing was done to ensure that the MIROxy 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 device is in compliance with the standards referenced and that it performs within its specifications.

The accuracy of SpO2 and pulse rate has been validated by *in vitro* testing using an optical simulator, under normal conditions.

The results obtained were within the 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
9200 Corporate Boulevard
Rockville MD 20850

Mr Simon Fowler
Sales Manager
M I R Medical International Research
Via del Maggiolino, 125
Roma
ITALY 00155

JAN 15 2009

Re: K081033
Trade/Device Name: MIROxi
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 17, 2008
Received: December 23, 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,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Division 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 (K):

Device Name: MIROxi

Indications for Use: The MIROxi pulse oximeter is intended to be used by a physician or by a patient under the instruction of a physician or paramedic.
The device is intended to test oximetry in people of all ages.

It 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

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