K130784

MEDICAL INTERNATIONAL RESEARCH

OCT 30 2013

510 (k) Summary

1. Applicant Information

Date Prepared:	Oct 30, 2013
Submitter:	MIR Medical International Research
Address:	Via del Maggiolino, 125
	00155 Roma – Italy
Contact Person:	Gerda Van Houts
Phone Number:	+39 06.22.754.777

2. Device Information

Trade Name:	Spirotel
As spirometer	
Classification Name:	Spirometer, diagnostic
Regulation Number	868.1840
Product code	BZG
As oximeter	
Classification Name	Oximeter
Regulation Number	870.2700
Product code	DQA

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

Company Name:	MIR Medical International Research
Device Name:	Spirotel
510(k) number:	K043528

4. Description of the device:

Spirotel is a pocket spirometer that can also feature a pulse oximeter function (optional).
It measures a range of functional respiratory parameters, and the oxygen saturation and pulse rate.
The device can operate completely autonomously or can be connected to a personal computer by means of various types of connections: USB, Bluetooth, GSM.

The device is identified as follows, according with the presence/absence of the options Bluetooth, GSM, SpO2:

Option	BT	GSM	SpO2	Ref. Code
-	No	No	No	9107000
SpO2	No	No	Yes	9107001
GSM	No	Yes	No	9107010
GSM + SpO2	No	Yes	Yes	9107011
BT	Yes	No	No	9107100
BT + SpO2	Yes	No	Yes	9107101
BT + GSM	Yes	Yes	No	9107110
BT + GSM + SpO2	Yes	Yes	Yes	9107111

Spirometry function

A turbine inside the device that uses the interruption of infra-red light as its operating principle, measures volume and flow rate.

Parameters measured

Symbol	Description	Units
FVC	Forced Vital Capacity	L
FEV1	Volume exhaled in 1st second of test	L
FEV1%	FEV1/FVC x 100	%
PEF	Peak expiratory flow	L/m
FEF-2575	Average flow between 25% and 75% of FVC	L/s

Oximetry function

The oximetry sensor features two light emitting diodes (LED), one emits visible red light and the other infra-red. Both bands of light pass through the finger to reach a light detector. During the passage through the finger, some of the light is absorbed by the blood and soft tissue depending on the concentration of haemoglobin. The amount of each light frequency absorbed depends on how oxygenated the blood is inside the tissue.

Technical specifications

Spirometry function

Flow/volume sensor	Bi-directional turbine
Temperature sensor	semiconductor (0-45°C)
Method of detection	Infra-red interruption
Maximum volume measured	10 L
Volume accuracy	± 3% or 50 mL
Flow rate measurement range	± 16 L/s
Flow rate accuracy	± 5% or 200 mL/s
Dynamic resistance at 12 L/s	<0.5 $cmH_2O/L/s$

Oximetry function

Method of detection	Red and infra-red light absorption
SpO2 measurement range	0 – 99% (with 1% increments)
SpO2 resolution	1%
SpO2 accuracy	± 2% (between 70-100% SpO2)
Pulse rate measurement range	30 – 300 BPM
Pulse rate resolution	1 BPM
Pulse rate accuracy	± 2 BPM or 2% whichever is greater

Bluetooth function

Operating frequency range	2402 – 2480 MHz
Number of antennas	1
Antenna type	Integrated ceramic chip antenna
Output power	0.1 mW

GSM function

Band	Quad-Band 850/900/1800/1900 MHz
Communication standard	EDGE (E-GPRS) multi-slot class 10
Antenna type	Internal
Antenna gain	gain 2.42 dBi

Other specifications

Power supply	Li-ion 3.7 V 1100mAh battery
Dimensions	88x74x38 mm;
Weight	151 g (including battery pack)

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 devices:

The new device has the following characteristics:

- light restyling of the enclosure to adapt to the new larger graphic display with touchscreen. Enclosure material is the same as the material used in **Spirodoc (K082766)**
- recheargeable battery
- same oximetry board and oximetry sensors as used in **Minispir (K122384)**
- data transmission based on new technologies as USB 2.0, Bluetooth (optional) and GSM/GPRS/EDGE (optional)
- new Main Board

Detailed description of the modification

Modification	Description of modification Spirotel (subject device)		predicate device name and 510(k) number
Enclosure	Light restyling of the enclosure to adapt to the new larger graphic display with touchscreen. Color is white with an orange stripe which goes all around the device. Material has changed to PC (orange part of the enclosure) and ABS + PC (white part of the enclosure).	 Same color as Same material as	 **Spirodoc (K082766)** **Spirodoc (K082766)**
Dimensions	74 x 88 x 38 mm	70 x 80 x 30 mm	**Spirotel (K043528)**
Weight	151 g	100 g	**Spirotel (K043528)**
Display	LCD backlit touch screen display, resolution 160 x 80	STN LCD, 2 lines x 16 alphanumeric characters	**Spirotel (K043528)**
Keyboard	None	Membrane, 5 keys	**Spirotel (K043528)**
Power supply	3.7V, 1100mA rechargeable lithium-ion battery	3V Lithium battery CR123A	**Spirotel (K043528)**
Oximetry board	MIR 046	Same board as	**Minispir (K122384)**
Oximetry sensors	BCI 1300 BCI 3026 BCI 3043 BCI 3078 BCI 3178 BCI 3444 BCI 3044	Same sensors as	**Minispir (K122384)**
Oximetry sensor connector	Mini HDMI	Same connector as	**Minispir (K122384)**
Spirometry Board	MIR 043 Processor: ATMEL UC3A0512 Memory: Flash AT49BV320D (4M) RTC: embedded in the ferro-magnetic RAM FM33256	MIR 007 Processor: Motorola 68HC11F1 Memory: SRAM TC551001 (1M) RTC: DS2417	**Spirotel (K043528)**
Data transmission	USB 2.0 Bluetooth (optional) GSM, GPRS, EDGE (optional)	RS 232 Acoustic coupling via telephone	**Spirotel (K043528)**

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 is substantially equivalent to the predicate device within the environments for which it is to be marketed.

Safety and environmental testing was conducted in accordance with EN 60601-1:2006 and EN 60601-1-2:2007. 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.

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 **oximetry parameters** SpO2 and pulse rate has been verified in-house using an optical simulator. The results obtained were within the range of accuracy required by FDA guideline on Pulse Oximeters and ISO 9919:2005.

A **battery testing** was performed on the rechargeable battery (3.7V, 1100mA lithium-ion battery) which replaces the primary cell battery (3V CR123A Lithium battery) of the predicate Spirotel, in order to verify charging performance in normal condition and safety in short-circuits condition. Test showed that duration of the battery is approximately the same as the predicate Spirotel.

USB 2.0 transmission replaces RS232 transmission of the predicate Spirotel. A verification of integrity of data transmitted via USB 2.0 to a Personal Computer has been carried out in-house and the results have shown that data were received without corruption.

Bluetooth transmission is performed using the proprietary module MIR 045 which has been FCC certified by a third party laboratory (FCCID: TUK-MIR045).
A verification of integrity of data transmitted via Bluetooth to a Personal Computer has been carried out in-house and the results have shown that data were received without corruption.

GSM/GPRS/EDGE transmission is performed using an FCC approved module.
A verification of the integration of the module into Spirotel has been carried out by the manufacturer of the module.
A verification of integrity of data transmitted (e-mail message with attached archive sent to a specific email address, or SMS message sent to a specific mobile phone) has been carried out in-house and the results have shown that data were received without corruption.

8. Conclusions
Based on these results, it is our determination that the device is substantially equivalent to the legally marketed device.

This summary on 510(k) substantial equivalence 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 Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2013

M.I.R. Medical International Research
Ms. Gerda Van Houts
Export Area Manager
Via Del Maggiolino, 125
Roma – Italy 00155

Re: K130784
Trade/Device Name: Spirotel
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG, DQA
Dated: September 12, 2013
Received: September 27, 2013

Dear Ms. Van Houts:

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.

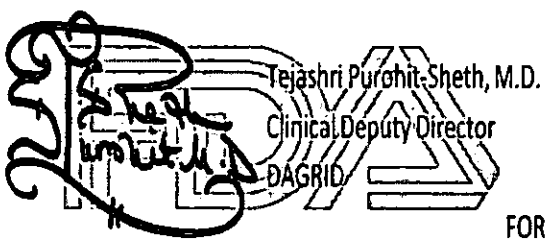
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130784

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____ (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)

James J. Lee

Digitally signed by James J. Lee
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=James J. Lee, 0.9.2342.19200300.100.1.1=2000954859
Date: 2013.10.30 10:13:42 -04'00'

for Anya Harry MD PhD