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

March 24, 2017

Monitored Therapeutics, Inc.
% Paul Dryden
Promedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K163249
Trade/Device Name: GoSpiro®
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: February 22, 2017
Received: February 24, 2017

Dear Paul Dryden:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K163249

Device Name

GoSpiro®

Indications for Use *(Describe)*

The GoSpiro® is intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. It is a single-patient use device.

Type of Use *(Select one or both, as applicable)*

☒ **XX** Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
March 21, 2017

Official Contact: William Zimlich, President
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Proprietary or Trade Name: GoSpiro®

Common/Usual Name: Diagnostic Spirometer

Classification Name: Diagnostic Spirometer
BZG, Class II, CFR 868.1840

Predicate Device: MIR Medical International Research - Spirobank G (K072979)
Reference Devices: MIR - Spirotel (K130784)
Micro Direct - Microlab (K031102)

Device Description:
The GoSpiro® is intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. It is a single-patient, use device.

The GoSpiro spirometer transmits real-time lung function data to computers, tablets or smartphones over a Bluetooth connection for tele-healthcare applications. The GoSpiro performs full flow-volume loops including inspiratory and expiratory data. The internal program performs all of the calculations for measurements to meet American Thoracic Society and European Respiratory Society requirements. It has built-in quality control measurements and transmits indices of measurement quality including time to peak flow, back-extrapolated volume, total expiratory time, and end-expiratory flow detection.

It is used with the GoSpiro App display and communications software on a smartphone or tablet.

The GoSpiro is powered by an internal rechargeable Lithium battery and is charged via its USB charging station connected to a USB power source. The device complies with ES 60601-1, IEC 60601-1-2, and IEC 60601-1-11.

The fundamental technology to measure flow is a vertical turbine volume sensor. The turbine transducer measures expired air directly at B.T.P.S. (body temperature and pressure with saturated water vapor) thus avoiding the requirement for temperature correction on exhalation. An electronic temperature sensor on the device PCB measures atmospheric temperature, thus enabling correction of inspired volumes and flows. This transducer is insensitive to the effects of condensation and temperature and avoids the need for individual calibration prior to performing a test.

Indications for Use:
The GoSpiro® is intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. It is a single-patient use device.

Contraindications:
Do not use the GoSpiro if you have any of the following unless your physician has cleared you to perform forced exhaled lung function measurements. Failure to obtain approval from your physician if you have any of these could result in serious injury or death:

- Hemoptysis (coughing up blood) of unknown origin
- Presence of a pneumothorax (collapsed lung)
- Presence of unstable cardiovascular status:
    - Recent (within one month) myocardial infarction (heart attack)
    - Uncontrolled hypertension (high blood pressure)
    - Pulmonary embolism (blood clot in your lungs)
    - History of a hemorrhagic cerebrovascular event (stroke)
    - Unstable Angina (chest pain)

- Recent thoracic (chest), abdominal or eye surgery (2 weeks)
- Nausea, vomiting or abdominal pain
- Thoracic or abdominal aneurysms (weak blood vessels in your chest or abdomen)
- History of syncope (fainting) associated with forced exhalation
- Active tuberculosis or Hepatitis B
- Unstable angina (chest pain)

Device Comparison

Table 1 compares the subject device to the predicate MIR Spirobank G (K072979) and the reference MIR Spirotel (K130784). The GoSpiro is similar to the Medical International Research predicate MIR Spirobank G (K072979) and the reference MIR Spirotel (K130784). The differences include: Oximetry measurements in the reference Spirotel, communication options including 3rd party display device, coaching features, display of information, and power source.

Table 1 – Comparison Predicate to Proposed Device

Technical feature/specification	**Predicate MIR Spirobank G (K072979)**	**Reference MIR Spirotel (K130784)**	**Proposed GoSpiro®**
Indications for Use	The Spirobank G spirometer 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 lung function and can make spirometry testing in people of all ages, excluding infants and neonates. It can be used in any setting.	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.	The GoSpiro® is intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. It is single-patient use device.
Environment of use	All settings	home, factory, pharmacy, hospital or physician's office.	physician's offices, clinics and home settings
Patient Population	People of all ages, excluding infants and neonates.	People of all ages	Adults and pediatric patients over 5 years old
Technology for measure flow and volume	Bidirectional Turbine	Bidirectional Turbine	Bidirectional Turbine
Energy Type	9V Alkaline battery	Rechargeable 3.7V, 1100 mAh Lithium battery	Rechargeable 3.7V, 500 mAh Lithium battery

Physical configuration	Touchscreen / LCD and membrane keys	Touchscreen / LCD	Touchscreen on smartphone or tablet and hard buttons
Technical feature/specification	**Predicate** **MIR Spirobank G (K072979)**	**Reference** **MIR Spirotel (K130784)**	**Proposed** **GoSpiro®**
Operating Conditions	Temperature – 10 – 40°C Humidity – 30% to 90% RH	Temperature: 10 – 40 °C Humidity: 30% to 90% RH	Temperature - 17 to 35°C Humidity - 30%RH to 75%RH
Weight	6.3 oz.	5.3 oz.	10.5 oz.
Size	1.3” x 1.9” x 6.4”	1.5” x 2.9” x 3.5”	3.5 x 4.5”
Flow Range	±16 l/s	±16 l/s	±14 l/s
Flow Accuracy	±5% or 200 mL/s	±5% or 200 mL/s	±5% or 200 mL/s
Flow Resistance	<0.5 cmH2O/L/s	<0.5 cmH2O/L/s	137 Pascals (Pa) per Liter per second, measured at 14 Liters per second (Lps)
Volume Range	0-10 liters	0-10 liters	0-8 liters
Volume accuracy	±3% or 50 mL, whichever is greater	±3% of reading, or 0.05 liters, whichever is greater.	±3% of reading, or 0.05 liters, whichever is greater.
Used with PFT filter and / or mouthpiece	Mouthpiece	Mouthpiece	Filter and mouthport
Communication	Bluetooth or USB	Bluetooth, USB or GSM/GPRS/EDGE	Bluetooth to Wi-Fi or Cellular
Coaching	Display of volume-time and flow-volume curves	Some instructions on screen, tone at 6 seconds, flow dependent tone frequency	Display of flow-time curves, 6 second count-down timer, tone at 6 seconds.
Feedback of test quality	Yes – Traffic lights for interpretation	Yes – Trend data and traffic lights for interpretation	Yes- Trend data
Test stored	Yes	Yes	Yes
Typical battery life per charge	- -	- -	Approximately 140 measurements
Auditory / visual alarms	Yes	Yes	Yes
Allows inspiration before forced exhalation	Yes	Yes	Yes

Technical feature/specification	Predicate MIR Spirobank G (K072979)	Reference MIR Spirotel (K130784)	Proposed GoSpiro®
Measurements Calculated and Displayed			
Tests Performed	*FVC	FVC	*FVC
	FEV *FEV1, *FEV6	FEV1	FEV0.75, *FEV1, FEV3, FEV6
	FEV/FVC (FER) for *1, 6		FEV/FVC (FER) for 0.75 /1 /3 / 6
	*PEF	PEF	*PEF
	MMEF		MMEF
	FEF 25/50/75		FEF 25/50/75
	*FEF 25-75%	FEF25-75 (MEF)	FEF25-75 (MEF)
	FIV1		FIV1
	*FIVC		FIVC
	PIF		PIF
			FIF25-75 (MIF25-75)
			FIF 25/50/75
			MET25-75
			FEV0.75/FEV6
	FEV1/FEV6		FEV1/FEV6
			FEF50/FVC
			MMEF/FVC (FEF25-75/FVC)
			FIV1/FIVC (FIR)
			R50 (FEF50/FIF50)
	*FET	Error Message	FET
	MVV		MVV (ind)
	Extrap Vol	Error Message	Vext
	Time to PEF	Error Message	Time to PEF
			Possible Cough
		Error Message	LAST500V
	Flow / Volume Curve		Flow / Volume Curve (on server)
	Volume / Time Curve		Volume / Time Curve (on server)
			Flow / Time Curve
ATS Spirometry guidelines	Yes	Yes	Yes
Standards Compliance	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	AAMI ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11
Water Ingress Protection	IPX1	IPX1	IP22
Biocompatibility and Patient Contact	Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure	Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure	Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure

* Indicates parameters displayed for patients only.

Many of the parameters calculated and displayed for the subject device are variations of the same parameter, e.g., FEV, in which time is the only variable. We recognize that the predicate has fewer measured and reportable parameters; therefore we have selected a reference device, Microlab – K031102 from MicroDirect that has similar indications for use and with more measured and reportable parameters.

Table 2 Comparison Reference to Subject Device

Technical feature/specification	**Reference Microlab / SpiroUSB – K031102**	**Proposed GoSpiro®**
Indications for Use	The Microlab spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.	The GoSpiro® is intended to be used by adults and children over 5 years old in physician's offices, clinics and home settings to conduct basic lung function and spirometry testing. It is single-patient use device.
Environment of use	hospitals, physician offices, laboratories and occupational health testing	physician's offices, clinics and home settings
Patient Population	4 – 17 – pediatric 18 – 99 - adults	Adults Pediatric patients over 5 years old
Technology for measure flow and volume	Turbine	Turbine
Energy Type	USB power	3.7V, 500 mAh Lithium battery
Physical configuration	Attached to PC	Data transmitted to tablet, computer or smartphone for
Operating Conditions	Temperature: 32 - 104F Humidity: 30% to 90% RH	Temperature - 17 to 35^{o}C Humidity - 30%RH to 75%RH Atmospheric pressure –
Weight	4.6 oz.	10.5 oz.
Size	2" x 2.4" x 3.5"	3.5 x 4.5"
Flow Range	Not specified	±14 l/s
Flow Accuracy	±3%	±5% or 200 mL/s
Flow Resistance	Not provided	137 Pascals (Pa) per Liter per second, measured at 14 Liters
Volume Range	Not specified	0-8 liters
Volume accuracy	±3%	±3% of reading, or 0.05 liters, whichever is greater.
Used with PFT filter and / or mouthpiece	Filter and mouthpiece	Filter and mouthport

Technical feature/specification	Reference Microlab / SpiroUSB – K031102	Proposed GoSpiro®
Communication	Direct USB connection	Bluetooth to mobile app
Test duration	Minimum of 15 seconds	15 to 20 seconds
Feedback of test quality	No	Not to user. Quality indicators transmitted to clinician.
Test stored	Yes on PC	Yes until transmitted and stored remotely
Typical battery life per charge	No battery	Approximately 140 measurements
Auditory / visual alarms	No	Blinking LED if no Bluetooth connection, graph displayed on smartphone or tablet, count-down
Allows inspiration before forced exhalation	Yes	Yes
Tests Performed	FVC	FVC
	FEV0.75, FEV1, FEV3, FEV6	FEV0.75, FEV1, FEV3, FEV6
	FEV/FVC (FER) for 0.75 /1 /3 / 6	FEV/FVC (FER) for 0.75 /1 /3 / 6
	PEF	PEF
	MMEF	MMEF
	FEF25-75 (MEF)	FEF25-75 (MEF)
	FIV1	FIV1
	FIVC	FIVC
	PIF	PIF
	FIF25-75 (MIF25-75)	FIF25-75 (MIF25-75)
	MET25-75	MET25-75
	FEV0.75/FEV6	FEV0.75/FEV6
	FEV1/FEV6	FEV1/FEV6
	FEF50/FVC	FEF50/FVC
	MMEF/FVC (FEF50/FVC)	MMEF/FVC (FEF25-75/FVC)
	FIV1/FIVC (FIR)	FIV1/FIVC (FIR)
	R50 (FEF50/FIF50)	R50 (FEF50/FIF50)
		FET
	MVV (ind)	MVV (ind)
		Vext
		PEAKTIME
		POSSIBLE_COUGH
		LAST500V
	Flow / Volume Curve	Flow / Volume Curve
	Volume / Time Curve	Volume / Time Curve
		Flow / Time Curve
	No	N/A

Technical feature/specification	Reference Microlab / SpiroUSB – K031102	Proposed GoSpiro®
Calculated	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
	N/A	N/A
ATS Spirometry guidelines	Yes	Yes
Standards Compliance	IEC 60601-1 IEC 60601-1-2	AAMI ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11
Biocompatibility and Patient Contact	Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure	Externally communicating (Indirect), Tissue and Surface Contact, Mucosa,

Substantial Equivalence Discussion

Indications for Use / Patient Population / Environment of Use:
As in comparison of Indications For Use above, we can conclude that the indications for use for the GoSpiro and the predicates are substantially equivalent.

The GoSpiro is for use in physician's offices, clinics and home settings whereas the predicate also included the hospital. The GoSpiro, predicate and references are prescription devices.

Design and Technology:
As discussed above, both devices have the same basic design for a handheld, portable turbine based spirometer which calculates volume, flow and time and then presents the data in typical pulmonary function parameters.

Discussion:
It is noted that the subject and predicate devices present almost all the same measured pulmonary function parameters to a patient self-testing at home and more parameters for the physician when displayed on a tablet. There are many different calculations that a clinician might wish to have, however they are all based upon flow, volume and time. The GoSpiro presents the total measured parameters similar to the reference device.

Performance and Specifications:
The performance and specifications demonstrate that the devices meet the ATS 2005 requirements for pulmonary function testing.

Compliance with Standards:
The GoSpiro complies with the currently recognized safety and EMC standards (AAMI/ANSI/ES 60601-1:2005+A1, IEC 60601-1-2:2007and IEC 60601-1-11:2015).

Performance Testing: Nonclinical / Bench:

The GoSpiro Spirometer was tested against criteria for:

- Environmental Requirements
- Modes of Operation
- Functional Requirements
  - ATS / ERS waveform simulator testing
  - High Altitude Performance
  - Flow Resistance
  - Possible Cough Detection
- Performance Requirements
  - Durability – turbine life test
- Mechanical Requirements
- Electrical Requirements
  - AAMI ANSI ES 60601-1
  - IEC 60601-1-11
  - IEC 60601-1-2
  - Battery Safety Testing IEC 62133
  - Wireless Coexistence Testing
  - Bluetooth Module Data Sheet
- PCB and Electrical Circuitry Requirements Packaging and Shipping Requirements
- Hardware Verification
  - Hardware verification
- Labeling Requirements
- Manufacturing Requirements
- Safety Requirements
- Cleaning and Shelf-life
- Software and System Verification and Validation (IEC 62304)
- Human Factors study

The GoSpiro passed the acceptance criteria for all the listed testing requirements and specifications.

Biocompatibility:
Biocompatibility has been tested and passed for all materials that come in contact with the patient directly or indirectly according to ISO 10993-1. The required tests performed were cytotoxicity (ISO 10993-5), irritation and sensitization (ISO 10993-10), Volatile Organic Compounds (VOC), CO, CO_2, Ozone, and $PM_{2.5}$ testing.

Substantial Equivalence Conclusion

Based upon the foregoing performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance we believe we have demonstrated that the GoSpiro is substantially equivalent and as safe and as effective as the predicate.