December 4, 2020

Monitored Therapeutics, Inc.
% Paul Dryden
President - consultant
Monitored Therapeutics, Inc. c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K202837
Trade/Device Name: GoSpiro®
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: November 3, 2020
Received: November 4, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202837

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
December 4, 2020

Sponsor: Michael Taylor - CEO
Monitored Therapeutics, Inc.
5995 Shier Rings Road, Ste A
Dublin, OH 43016
Tel: +614-761-3555

Submission Correspondent: Paul Dryden
ProMedic, LLC

Proprietary or Trade Name: GoSpiro®

Common/Usual Name: Diagnostic Spirometer

Regulation Number: 21CFR 868.1840
Regulation Code: Diagnostic Spirometer
Product Code: BZG
Regulatory Class: II

Predicate Device: Monitored Therapeutics, Inc. – K163249 – GoSpiro®

Modification:
Changing the turbine from single patient, multi-use to multi-patient, multi-use.

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.

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.

Device Comparison:
Table 1 compares the subject device to the predicate Monitored Therapeutics – GoSpiro®, K163249.

Table 1 – Comparison Predicate to Proposed Device

Technical feature/specification	**Predicate** **K163249 - GoSpiro®**	**Proposed** **GoSpiro®**
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 single-patient use device.	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.
Environment of use	Physician's offices, clinics and home settings	Physician's offices, clinics and home settings
Patient Population	Adults and pediatric patients over 5 years old	Adults and pediatric patients over 5 years old
Use with PFT filter after each use	Yes	Yes
Turbine may be cleaned / disinfected	No, had to be replaced if no filter was used	Cleaned and Disinfected
Technology for measure flow and volume	Bidirectional Turbine	Bidirectional Turbine
Energy Type	Rechargeable 3.7V, 500 mAh Lithium battery	Rechargeable 3.7V, 500 mAh Lithium battery
Physical configuration	Touchscreen on smartphone or tablet and hard buttons	Touchscreen on smartphone or tablet and hard buttons
Operating Conditions	Temperature - 17 to 35^{o}C Humidity - 30%RH to 75%RH	Temperature - 17 to 35^{o}C Humidity - 30%RH to 75%RH
Weight	10.5 oz.	10.5 oz.
Size	3.5 x 4.5"	3.5 x 4.5"
Flow Range	±14 l/s	±14 l/s
Flow Accuracy	±5% or 200 mL/s	±5% or 200 mL/s
Flow Resistance	137 Pascals (Pa) per Liter per second, measured at 14 Liters per second (Lps)	137 Pascals (Pa) per Liter per second, measured at 14 Liters per second (Lps)
Volume Range	0-8 liters	0-8 liters

Technical feature/specification	Predicate K163249 - GoSpiro®	Proposed GoSpiro®
Volume accuracy	±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	Yes	Yes
Communication	Bluetooth to Wi-Fi or Cellular	Bluetooth to Wi-Fi or Cellular
Coaching	Display of flow-time curves, 6 second count-down timer, tone at 6 seconds.	Display of flow-time curves, 6 second count-down timer, tone at 6 seconds.
Feedback of test quality	Yes- Trend data	Yes- Trend data
Test stored	Yes	Yes
Typical battery life per charge	Approximately 140 measurements	Approximately 140 measurements
Auditory / visual alarms	Yes	Yes
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
	FEF 25/50/75	FEF 25/50/75
	FEF25-75 (MEF)	FEF25-75 (MEF)
	FIV1	FIV1
	FIVC	FIVC
	PIF	PIF
	FIF25-75 (MIF25-75)	FIF25-75 (MIF25-75)
	FIF 25/50/75	FIF 25/50/75
	MET25-75	MET25-75
	FEV0.75/FEV6	FEV0.75/FEV6
	FEV1/FEV6	FEV1/FEV6
	FEF50/FVC	FEF50/FVC
	MMEF/FVC (FEF25-75/FVC)	MMEF/FVC (FEF25-75/FVC)
	FIV1/FIVC (FIR)	FIV1/FIVC (FIR)
	R50 (FEF50/FIF50)	R50 (FEF50/FIF50)
	FET	FET
	MVV (ind)	MVV (ind)
	Vext	Vext
	Time to PEF	Time to PEF
	Possible Cough	Possible Cough
	LAST500V	LAST500V
	Flow / Volume Curve (on server)	Flow / Volume Curve (on server)
	Volume / Time Curve (on server)	Volume / Time Curve (on server)
	Flow / Time Curve	Flow / Time Curve

Technical feature/specification	Predicate K163249 - GoSpiro®	Proposed GoSpiro®
ATS Spirometry guidelines	Yes	Yes
Standards Compliance	AAMI ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11	AAMI ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11
Water Ingress Protection	IP22	IP22
Biocompatibility and Patient Contact	Externally communicating (Indirect), Tissue and Surface Contact, Mucosa, limited exposure	Similar patient contact and identical materials
Cleaning and Disinfection validation	Cleaning of mouthport	Same mouthport Cleaning and disinfection of Turbine

* Indicates parameters displayed for patients only.

Differences vs. Predicate:
The only difference between the predicate and the subject device is the labeling to allow for cleaning, disinfection and reuse of the turbine. The validation testing has been performed demonstrating that the turbine may be cleaned, disinfected and reused.
All other features and specifications are identical to the cleared K163249 device.

Substantial Equivalence Discussion:
As the devices are identical the only discussion relates to the change in the ability to clean, disinfect and reuse the turbine for multi-patient, multi-use. Disinfection is only required when a filter is not used with each patient.

All other comparative features are identical.

- Indications for Use / Patient Population / Environment of Use
- Prescriptive
- Design and Technology
- Performance and Specifications
- Compliance with Standards
- Performance Testing
    - High level disinfection validation
    - Post-disinfecting performance
    - Post-disinfecting biocompatibility
- Biocompatibility
    - The materials have been evaluated per ISO 10993-1

Substantial Equivalence Conclusion:
The GoSpiro® is substantially equivalent to the cleared GoSpiro® predicate, K163249.