February 15, 2019

eReserchTechnology GmbH
% Dawn Tibodeau
Third Party 510(k) Project Coordinator
Tuv Sud America Inc.
1775 Old Highway 8 Nw
New Brighton, Minnesota 55112-1891

Re: K173937
Trade/Device Name: SpiroSphere
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: BTY
Dated: December 21, 2018
Received: December 31, 2018

Dear Dawn Tibodeau:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173937

Device Name
SpiroSphere

Indications for Use *(Describe)*
The SpiroSphere is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older.

It can be used by physicians in the office or hospital.

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

☒ 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.

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GENERAL INFORMATION

1 Type of Submission

Traditional 510(k) Submission/Third Party Review

Submission date: 07/28/2017

2 Submitter

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3 Establishment Registration Number

3008505660

4 Common Name or Classification Name

Predicted pulmonary-function value calculator
(CFR 868.1890, Product Code BTY)

5 Trade Name

SpiroSphere

6 Device Classification

This is a Class II device

7 Classification Panel

73 Anesthesiology Part 868 Code BTY

8 Reason for Premarket Notification

Introducing a (finished) device into commercial distribution (marketing) in the U.S. for the first time.

9 Legally predicate marketed device

SpiroPro
K000648 Code BTY

Reference Device
SpiroPro with BT
K092324 Code BTY, Code DQA

10 Predicate Device Company

eResearchTechnology GmbH (device was formally listed by Erich Jaeger GmbH and Carefusion Germany 234 GmbH)

11 Device Description

The SpiroSphere is a compact spirometry device. It`s Sensor Unit is battery-powered. The Main Unit can be powered by battery or power supply. The SpiroSphere is used to measure inspiratory and expiratory lung function parameters in adults and children 4 years and older. The measured data is saved into the device and can be read out at any time.

A printer can be connected with the SpiroSphere and all needed data (e.g. reports, Screenshots) can be printed. Moreover it is possible to transfer data by USB, Wifi, 3G, and Ethernet.

Pulmonary functions

- Slow Spirometry
- Forced Spirometry
- Flow-Volume loop and Volume-Time tracing, pre/post tests
- Trending capabilities

12 Indications for Use

The SpiroSphere is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older.
It can be used by physicians in the office or hospital.

13 Required Components

Power Supply (medical grade)
Pneumotach with Mouthpiece (ERT PT)

Instruction for Use
NoseClips

14 Summary Table of Comparison

Comparison with SpiroPro (K000648) and SpiroPro with BT (K092324)

	Predicate Device SpiroPro (K000648)	**Reference Device SpiroPro with BT (K092324)**	**SpiroSphere**
Intended Use / Indications for Use	The SpiroPro is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients at home. The SpiroPro measures inspiratory and expiratory lung function parameter in adults and children from 4 years on according the ATS recommendations for diagnostic devices. Results are displayed graphical and numerical on the display of the device. Optional the results can be printed on an external printer or transferred to a PC. SpiroPro can save all data in the internal non-volatile memory for later retrieval, print-out or transfer to a PC.	The SpiroPro is a portable, battery operated device and can be used by physicians in the office or hospital, in occupational medicine or by patients in the home. The SpiroPro measures inspiratory and expiratory lung function parameters in adults and children 4 years and older. In addition to the pulmonary function measurements, oxygen saturation and heart rate can be recorded.	The SpiroSphere is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older. It can be used by physicians in the office or hospital.
Patient population	Adults and children 4 years and older	Adults and children 4 years and older	Adults and children 4 years and older
Operation principle	- Measurement of inspiratory and expiratory flows and volumes with pneumotach transducer - Calculation of lung function parameters - Results are displayed and stored, they can be printed and exported	- Measurement of inspiratory and expiratory flows and volumes with pneumotach transducer - Calculation of lung function parameters - Results are displayed and stored, they can be printed and exported	- Measurement of inspiratory and expiratory flows and volumes with pneumotach transducer - Calculation of lung function parameters - Results are displayed and stored, they can be printed and exported
Measurements	FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and	FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and	FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and

	others acc. to ATS*	others acc. to ATS*	others acc. to ATS*
***ATS conformity (criteria)**	1994 ATS/ERS Spirometry Standards	2005 ATS/ERS Spirometry Standards	2005 ATS/ERS Spirometry Standards
Fundamental scientific technology	Pneumotachograph, pressure to flow conversion technique (Lilly Type Pneumotachograph)	Pneumotachograph, pressure to flow conversion technique (Lilly Type Pneumotachograph)	Pneumotachograph, pressure to flow conversion technique (Lilly Type Pneumotachograph)
Components	Mouthpiece (single patient use)	Mouthpiece (single patient use)	Mouthpiece (single patient use)
	Pneumotach (single patient use)	Pneumotach (single patient use)	Pneumotach (single patient use)
	Medical Grade Power Supply	Medical Grade Power Supply	Medical Grade Power Supply
Screen Display	54 x 35 mm	54 x 35 mm	162 x 122 mm
Interface	RS232 Interface	USB, RS232 Interface and Bluetooth interface	Bluetooth USB Wifi/Ethernet 3G
Energy type	Li-Ion Battery	Li-Ion Battery	Main Unit: Li-Ion Battery and Power Supply
			Sensor Unit Unit: Li-Ion Battery
Bluetooth interface	None	WML-C46 (Mitsumi)	Sensor Unit: Silicon Laboratories, BT121
Wi-Fi/BT interface	None	None	Main Unit: Texas Instruments WL18xxMOD
Ethernet	None	None	10/100 MBit Ethernet
3G Interface	None	None	Sierra Wireless HL 8548

15 Comparison Summary

Intended Use

The intended use of the SpiroSphere device is the same as in the predicate device SpiroPro.

Technological Characteristics

The predicate device SpiroPro and the reference device SpiroPro with BT are presently in commercial distribution globally including the United States of America. The SpiroSphere has the same fundamental scientific

technology and is substantial equivalent in function and application to the predicate device.

Biocompatibility

No new issues of biocompatibility have been raised with regard to the SpiroPro.

Differences

- The SpiroSphere consists of a main unit for display and a sensor unit for measurement.
- The SpiroSphere provides a high resolution, color touch screen instead of a high-resolution graphical LCD touch screen
- The SpiroSphere provides additional state of the art interfaces (Bluetooth, 3G, Wi-Fi, Ethernet, USB) to enable communication.
- The SpiroSphere provides additional Predicted Values (GLI 2012)
- SpiroSphere complies to the 2005 ATS/ERS Spirometry Standards

16 Summary of Device Testing

The following practices were followed and monitored for development of the SpiroSphere:

- The device was developed and tested according to GMP Standard Operating Procedures for Medical Devices.
- Software verification and validation was done in accordance with IEC 62304:2006.
- Risk analysis of the SpiroSphere was performed according to ISO 14971:2007.
- Tests were performed to confirm that the SpiroSphere meets the recommendations for accuracy and precision for Spirometry of the American Thoracic Society (ATS) according to ATS/ERS standards 2005.
- The electrical safety testing was performed according to IEC 60601-1:2012 to demonstrate conformance with the requirements for basic safety and essential performance.

- The Electro Magnetic Compatibility testing was performed according to IEC 60601-1-2:2014.

- The FDA Guidance “Radio Frequency Wireless Technology in Medical Devices” from 2013 was considered for the 3G/BT/WIFI functions and all requirements are fulfilled.

- Human Factors/Usability Engineering validation was done according to IEC 62366 Edition 1.1: 2014.

- Biocompatibility was evaluated in accordance with ISO 10993-1:2009 and ISO 18562:2017

- The FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” from 2014 has been considered in the device design and all requirements are fulfilled.

- Final Guidance for Industry and FDA Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling from 2015 has been considered.

17 Conclusion

Based on the intended use of the SpiroSphere and the results of the electronic safety testing and performance testing provided in the 510(k), the SpiroSphere is found to be substantially equivalent to the predicate device SpiroPro.

The non-clinical data as well as the hardware and software verification and validation demonstrate that the SpiroSphere device should perform as intended in the specified use conditions.

eResearchTechnology GmbH believes that the SpiroSphere is substantially equivalent to the current legally marketed device SpiroPro. The SpiroSphere has the same technological characteristics and was determined to be as safe and as effective as the predicate device.