January 28, 2021

eResearchTechnology GmbH
Margit Kohlen
Design Assurance Engineer
Sieboldstrasse 3
Estenfeld, Bavaria 97230
Germany

Re: K202754
Trade/Device Name: MasterScope WSSU
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: BTY, DPS
Dated: December 15, 2020
Received: December 21, 2020

Dear Margit Kohlen:

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Indications for Use *(Describe)*

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.

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GENERAL INFORMATION

1 Type of Submission

Traditional 510(k) Submission

Submission date: 01/28/2021

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)

Electrocardiograph (CFR 870.2340, Product Code DPS)

5 Trade Name

MasterScope WSSU

6 Device Classification

This is a Class II device

7 Classification Panel

73 Anesthesiology Part 868 (Code BTY)

74 Circular System Devices, ECG Part 870 (Code DPS)

8 Reason for Premarket Notification

New option to an existing eResearchTechnology device

9 Legally predicate marketed device

MasterScope / MasterScope ECG / MasterScope CT

K082539 Code BTY, DPS

Reference device

SpiroSphere
K173937 Code BTY

10 Predicate Device Company

eResearchTechnology GmbH

11 Device Description

The MasterScope is a portable device, which can collect spirometry and ECG data.

With the option Spirometry, inspiratory and expiratory lung function measurements can be performed with a wired sensor (Digital Handle USB) or wireless spirometry sensor unit (WSSU Bluetooth). Both spirometry sensors work with a pneumotach (Lilly Type Pneumotachograph).

The Wireless Spirometry Sensor Unit is battery-powered and can be charged with a dedicated charging station.

With the option ECG, a 12-channel surface electrocardiogram (ECG) can be measured and recorded. It is not intended for intracardial use.

The interpretation software is intended to support the physician in evaluation the ECG in terms of morphology and rhythm.

The MasterScope software allows protocol-driven workflows and can be customized for use in clinical trials (e.g. individual access rights).

MasterScope provides automated and secure data transmission to a centralized data base.

The measured data is saved into the MasterScope software and can be read out at any time.

A printer can be connected with the notebook and all needed data can be printed. Moreover it is possible to transfer data by USB, Wifi, and Ethernet.

The MasterScope WSSU is powered from 100 - 240V / 50 - 60Hz wall outlets. No energy is transferred to the patient.

Possible Configurations:

MasterScope will be delivered in the following configurations:

- MasterScope WSSU:
  - Notebook with Wireless Spirometry Sensor Unit (incl. Charging Station)
  - Notebook with Wireless Spirometry Sensor Unit (incl. Charging Station) and ECG Amplifier

- MasterScope ECG:
  - Notebook with ECG Amplifier

a) pulmonary functions
- Measurement with pneumotachograph
- Slow spirometry
- Forced spirometry
- Flow-Volume and Volume- Time Loop, pre/post tests
- Trending capabilities
- Patient Incentive animations

b) ECG functions
- Simultaneous acquisition of the 12 standard leads
- Storage of 10 seconds of acquired ECG signal
- Digital filters for base-line drift and mains interference suppression
- Interpretation program Hanover ECG System (HES) providing the following additional information:
  - Representatives templates of each lead including markers on fiducially points
  - Summary of mean measurements
  - Rhythm Analysis statements
  - Signal noise detection and information
  - Specific findings on QRS complex
  - Conduction statements
  - QRS T diagnostic statements
  - Arrhythmia monitoring detection
  - Heart Rate Variability

12 Intended Use Statement

MasterScope WSSU is a medical device to measure inspiratory and expiratory lung function parameters. With the option ECG a 12-channel surface electrocardiogram (ECG) can be measured and recorded. It is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients.

A qualified physician has to reassess all MasterScope/MasterScope ECG measurements. An interpretation by MasterScope/MasterScope ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the MasterScope/MasterScope ECG represent partial quantitative information on the patient's cardiovascular conditions and no therapy or drugs can be administered based solely on the interpretation statements.

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

The MasterScope spirometry and ECG application is intended to measure adults and children aged 4 years and older. The patients must be able to understand and perform instructions of the physician.

13 Required Components

Notebook (MasterScope Software)
Instruction for Use

MasterScope WSSU:

- Wireless Spirometry Sensor Unit (WSSU)
- Pneumotach with Mouthpiece (ERT PT)
- Charging Station (WSCS) with Power Supply (medical grade)
- Calibration syringe (manufacturer Vyaire)
- Nose clips (manufacturer Quosina)

MasterScope ECG:

- ECG Amplifier
- ECG electrodes (manufacturer AMBU or Welch Allyn)

14 Summary Table of Comparison

Comparison with MasterScope CT (K082539) and SpiroSphere (K173937)

The Sensor Unit used in MasterScope WSSU device is cleared under SpiroSphere (K173937). The Sensor Unit is supplied in its final finished form and is identical to the reference predicate device.

Pulmonary Function Comparison			
	Predicate Device MasterScope CT (K082539)	**Reference Device SpiroSphere (K173937)**	**MasterScope WSSU**
Indications for Use	The MasterScope / MasterScope ECG is intended to be used for measurement and data collection of lung function parameters. The system performs cooperation-dependent flow volume measurements. Mostly it will be used for COPD and Asthma patients. In addition it is intended for measuring a 3/6- or 12-channel surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on the screen or printed on paper. 12-channel ECG's are analysed automatically and suggestions for the interpretation of the 12-channel ECG can be made by the software. MasterScope / MasterScope ECG can be used for non interpretive applications for patients with an age of 4 years and older and a weight of 20 kg or higher. MasterScope / MasterScope ECG is intended for use in routine ECG recording by trained physicians in the office or hospital. MasterScope / MasterScope ECG is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients. MasterScope CT (Clinical Trial version) incorporates the identical measurements. In addition it offers	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.	MasterScope is a medical device to measure inspiratory and expiratory lung function parameters. With the option ECG a 12-channel surface electrocardiogram (ECG) can be measured and recorded. It is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients. A qualified physician has to reassess all MasterScope/MasterScope ECG measurements. An interpretation by MasterScope/MasterScope ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the MasterScope/MasterScope ECG represent partial quantitative information on the patient's cardiovascular conditions and no therapy or drugs can be administered based solely on the interpretation statements. It can be used by physicians in the office or hospital.

Pulmonary Function Comparison			
	Predicate Device MasterScope CT (K082539)	**Reference Device SpiroSphere (K173937)**	**MasterScope WSSU**
	workflow control elements to restrict the use of the equipment (e.g. individual access rights are defined for different user roles like investigator, doctor, study nurse, trainer and service personnel). The interpretation software is intended to support the physician in evaluation the ECG in terms of morphology and rhythm. A qualified physician has to reassess all MasterScope / MasterScope ECG measurements. An interpretation by MasterScope / MasterScope ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the MasterScope / MasterScope ECG represent partial qualitative and quantitative information on the patient's cardiovascular condition and no therapy or drugs can be administered based solely on the interpretation statements. The MasterScope / MasterScope ECG / MasterScope CT is powered from 100 - 240V / 50 - 60Hz wall outlets. No energy is transferred to the patient.		The MasterScope spirometry and ECG application is intended to measure adults and children aged 4 years and older. The patients must be able to understand and perform instructions of the physician.
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
Measure-ments	FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and others acc. to ATS*	FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and others acc. to ATS*	FEV1, FVC, PEF, FEF25-75, VC, IC, ERV and others acc. to ATS*

Pulmonary Function Comparison			
	Predicate Device MasterScope CT (K082539)	**Reference Device SpiroSphere (K173937)**	**MasterScope WSSU**
Performance Specifications	Measuring Range - PEF: 0 to +/- 16 L/s - FEV1 and FVC: 0.1 to 8 L Accuracy - PEF: 0 to 14 L/s: +/- 5 %/0.2 L/s - FEV1 and FVC: 0.5 to 8 L: +/- 3 %/0.05 L Resolution - PEF: 10 mL/s - FEV1 and FVC: 1 mL	Measuring Range - PEF: 0.1 to 16 L/s - FEV1 and FVC: 0.1 to 8 L Accuracy - PEF: 0,1 to 16L/s: ±10% of reading or +/-0,3 L/s - FEV1 and FVC: 0,1 to 8 L: ± 3% of reading or +/- 0,050 L Instantaneous flow: 0.1 - 14 L/s: ± 5% or 0.2 L/s Resolution - PEF: < 5 mL/s - FEV1 and FVC: 1 mL	Measuring Range - PEF: 0.1 to 16 L/s - FEV1 and FVC: 0.1 to 8 L Accuracy - PEF: 0.1 to 16 L/s: +/- 10% of reading or +/- 0,3 L/s - FEV1 and FVC: 0.1 to 8 L: +/- 3% of reading or +/- 0,050 L Instantaneous flow: 0.1 - 14 L/s: ± 5% or 0.2 L/s Resolution - PEF: < 5 mL/s - FEV1 and FVC: 1 mL
***ATS conformity (criteria)**	2005 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	Pneumotach (single patient use)	ERT Pneumotach (single patient use)	ERT Pneumotach (single patient use)
	USB connection to PC	Medical Grade Power Supply (Main Unit)	Medical Grade Power Supply (Charging Station)
Screen Display	162 x 122 mm or higher	162 x 122 mm	identical
Interface Sensor	USB	Bluetooth	Bluetooth
Energy type	Digital Handle USB Cable connection	Sensor Unit Li-Ion Battery charged via main unit	Sensor Unit Li-Ion Battery charged via Charging Station

Comparison with MasterScope ECG (K082539)

ECG Function Comparison		
	MasterScope ECG (K082539)	**MasterScope WSSU with ECG**
Intended Use / Indications for Use	MasterScope is a medical device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older. With the option ECG a 12-channel surface electrocardiogram (ECG) can be measured and recorded. It is not intended for intracardial use. MasterScope is a portable, mains power independent, active diagnostic medical device for transient application (≤ 60 min). It can be used by physicians in the office or hospital.	MasterScope is a medical device to measure inspiratory and expiratory lung function parameters. With the option ECG a 12-channel surface electrocardiogram (ECG) can be measured and recorded. It is not intended for intracardial use. Automatic interpretation of the ECG is not possible for pediatric patients with an age below 16 years and for pacemaker patients. A qualified physician has to reassess all MasterScope/MasterScope ECG measurements. An interpretation by MasterScope/MasterScope ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the MasterScope/MasterScope ECG represent partial quantitative information on the patient's cardiovascular conditions and no therapy or drugs can be administered based solely on the interpretation statements. It can be used by physicians in the office or hospital. The MasterScope spirometry and ECG application is intended to measure adults and children aged 4 years and older. The patients must be able to understand and perform instructions of the physician.
Patient population	Adults and children 4 years and older	Adults and children 4 years and older
Operation principle	Measurement of 12-channel surface electrocardiogram	Measurement of 12-channel surface electrocardiogram
Application Time	Transient application (≤ 60 min)	Transient application (≤ 60 min)
ECG leads	acc. to Einthoven, Wilson, Goldberger	acc. to Einthoven, Wilson, Goldberger
Leads	12 standard	12 standard
Bandwidth	0 - 150 Hz digital	0 - 150 Hz digital
A/D resolution	2.6 µV/bit ECG, 19 bit	2.6 µV/bit ECG, 19 bit
Sampling rate per channel	1000 Hz	1000 Hz

Sampling rate for pacemaker detection	4000 Hz	4000 Hz
Data transfer/ connection to PC	USB connection	USB connection
Power supply	5V DC via USB interface	5V DC via USB interface
Connection to electrodes	4 mm snap connector, gold plated	4 mm snap connector, gold plated
Patient contacting accessories	• Single use electrode • Electrode cable	• Single use electrode • Electrode cable
ECG Amplifier enclosure material	ABS/PC (no patient contacting part)	ABS/PC (no patient contacting part)
ECG interpretation software	Hannover ECG system (HES)	Hannover ECG system (HES)

15 Summary of Device Testing

The following practices were followed and monitored for development of the MasterScope WSSU

- 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 Ed.1.1:2015.
- Risk analysis of the MasterScope and WSSU was performed according to ISO 14971:2007.
- Tests were performed to confirm that the MasterScope WSSU 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 according to IEC 62366-1: 2015, IEC 60601-1-6:2013, and the FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices” from 2016 demonstrated the safety and efficacy of the device.
- Material Certification provided to support Biocompatibility evaluation in accordance with ISO 10993-1:2009 and ISO 18562-1:2017.
- 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.
- The electrical safety testing for ECG was performed according to IEC 60601-2-25:2011 to demonstrate conformance with the requirements for basic safety and essential performance of electrocardiographs

16 Comparison Summary

Intended Use

The intended use of the MasterScope WSSU device is comparable to the predicate device MasterScope CT–the MasterScope WSSU can also be connected with an option for ECG measurement.

Technological Characteristics

The predicate device MasterScope CT is presently in commercial distribution globally including the United States of America. The MasterScope WSSU has the similar technological characteristics and is similar in design, function, and application to the predicate device.

The technological characteristics are the same as the predicate device.

Biocompatibility

There have been no changes in material and biocompatibility.

All material used is identical to referenced device. Manufacturing process is identical to referenced device.

The Wireless Spirometry Sensor Unit and ERT PT are exactly the same as already used in the referenced device SpiroSphere.

Therefore, now new issues of biocompatibility are raised with regard to the referenced device.

Differences

- The intended use of MasterScope CT, MasterScope WSSU and SpiroSphere devices are identical to the fact that they are compact/portable diagnostic devices to measure inspiratory and expiratory lung function parameters in adults and children. All devices can be used by physicians in the office or hospital. MasterScope CT and MasterScope WSSU can be optionally delivered with an additional ECG amplifier.
- The MasterScope WSSU is using a wireless sensor instead of the USB Digital Handle to measure inspiratory and expiratory lung function parameters. MasterScope WSSU connects the sensor unit to a notebook via Bluetooth. MasterScope CT using a Digital Handle with USB connection to the notebook. Thus, with both models the sensor is connected to a notebook with MasterScope Software installed.

The software on the notebook shows the same user interface for both models. The Bluetooth connection was tested for EMC and wireless coexistence. There is no impact on usability, safety or efficacy of the device.

- The Digital Handle receives the power via the USB cable from the notebook, which is connected to a mains plug.
  The wireless sensor unit of MasterScope WSSU and Spirosphere is equipped with a Li-Ion Battery for power supply. The battery is charged via a charger. SpiroSphere has a charger implemented in the Main Unit that is connected to a mains plug via a Medical Grade Power Supply.
  MasterScope WSSU is delivered with a separate charging station, which is connected to a mains plug via a Medical Grade Power Supply. The design of this charging station is adapted to the implemented one in SpiroSphere Main Unit and uses the same technology. The devices conformed to IEC60601-1:2012.

- The display is specified with minimum the same size as for SpiroSphere (162 x 122 mm) or higher, dependent on the notebook type. The display of user interface and measurement results will be adapted to the screen size for readability. No influence on usability or safety and efficacy was found.

17. Conclusions

Based on the intended use of the MasterScope WSSU and the results of the non-clinical, bench testing and performance testing provided in the 510(k), the MasterScope WSSU is found to be substantially equivalent to the predicate device MasterScope CT.