May 28, 2024

eResearchTechnology GmbH
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K223629
Trade/Device Name: SpiroSphere, SpiroSphereECG, CardioSphere
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: BTY, DPS
Dated: June 5, 2023
Received: June 5, 2023

Dear Prithul Bom:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jennifer W. Shih -S

Jennifer Shih Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*
K223629

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.

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."

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)*
K223629

Device Name
SpiroSphere ECG

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.

With the option ECG, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use.

A qualified physician has to reassess all ECG measurements. An interpretation by SpiroSphere ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the SpiroSphere 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 SpiroSphere ECG is not intended for use in an EMS environment (Emergency Medical Services Environment).

The minimum age for ECG application is 4 years.

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)

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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)*
K223629

Device Name
CardioSphere

Indications for Use *(Describe)*
With the CardioSphere, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use.

A qualified physician has to reassess all ECG measurements. An interpretation by CardioSphere is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the CardioSphere 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 CardioSphere is not intended for use in an EMS environment (Emergency Medical Services Environment).

The minimum age for ECG application is 4 years.

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)

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GENERAL INFORMATION

1 Type of Submission

Traditional 510(k) Submission

Date 510(k) summary prepared: 21APR2023

2 Submitter

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Phone/Fax:	+1 609 779 5935
E-mail	todd.kisner@clario.com

3 Establishment Registration Number

3008505660

4 Common Name or Classification Name

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

Electrocardiograph (CFR 870.2340, Product Code DPS)

5 Trade Names

SpiroSphere

SpiroSphere ECG

CardioSphere

6 Device Classification

Class II

7 Classification Panel

73 Anaesthesiology Part 868 Code BTY (primary)

74 Cardiovascular Part 870 Code DPS (secondary)

8 Reason for Premarket Notification

New option (ECG) to a cleared device (SpiroSphere K173937)

9 Legally Marketed Predicate and Reference Devices

Predicate Device:
K202754 Code BTY, DPS
Masterscope, Masterscope ECG, Masterscope CT, Masterscope WSSU

Reference Devices:

K173937 Code BTY
SpiroSphere

K183369 Code DPS
COR12

10 Predicate Device Company

eResearchTechnology GmbH

Reference Device Companies

eResearchTechnology GmbH (SpiroSphere)

Corscience GmbH & Co. KG (COR12)

11 Device Description

SpiroSphere

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

SpiroSphere ECG

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

With the ECG option (subject of this 510(k)), 12-channel surface electrocardiogram can be measured and recorded.

CardioSphere

The Main Unit can be powered by battery or power supply. The Main Unit is wirelessly connected to an ECG amplifier via Bluetooth.

With the ECG option (subject of this 510(k)), 12-channel surface electrocardiogram can be measured and recorded.

A printer can be connected and data (e.g. reports, screenshots) can be printed. Moreover, it is possible to transfer data by USB, Wifi, 3G, and Ethernet connections.

Pulmonary function assessments

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

Cardiovascular assessments

- 12 Lead Electrocardiogram

12 Intended Use/Indications for Use - SpiroSphere

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 Intended Use/Indications for Use – SpiroSphere ECG

The SpiroSphere ECG is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older.

With the option ECG, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use.

A qualified physician has to reassess all ECG measurements. An interpretation by SpiroSphere ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the SpiroSphere 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 SpiroSphere ECG is not intended for use in an EMS environment (Emergency Medical Services Environment).

The minimum age for ECG application is 4 years.

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

14 Intended Use/Indications for Use - CardioSphere

With the CardioSphere, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use.

A qualified physician has to reassess all ECG measurements. An interpretation by CardioSphere is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the CardioSphere 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 CardioSphere is not intended for use in an EMS environment (Emergency Medical Services Environment).

The minimum age for ECG application is 4 years.

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

15 Required Components

Power Supply (medical grade)
Instructions for Use

SpiroSphere and SpiroSphere ECG:
Pneumotach with Mouthpiece (ERT PT)
Nose Clips

SpiroSphere ECG and CardioSphere:
ECG Unit/amplifier
ECG electrodes

16 Summary Table of Comparison

Comparison tables with Predicate and Reference devices: MasterScope (K202754), COR12 (K183369), and SpiroSphere (K173937)

Pulmonary / Spirometry Function Comparison				
	Predicate Device MasterScope (K202754)	**Reference Device SpiroSphere (K173937)**	**Subject Device**	
			SpiroSphere ECG	**SpiroSphere**
Intended Use / Indications for Use	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	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.	The SpiroSphere ECG is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older. With the option ECG, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for	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/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.		pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use. A qualified physician has to reassess all ECG measurements. An interpretation by SpiroSphere ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the SpiroSphere 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 SpiroSphere ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The minimum age for ECG application is 4 years. It can be used by physicians in the office or hospital.	
Patient population	4 years and older	4 years and older	Identical	Identical

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	Identical	Identical
Measurements	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*	Identical	Identical
***ATS conformity (criteria)**	2005 ATS/ERS Spirometry Standards	2005 ATS/ERS Spirometry Standards	Identical	Identical
Fundamental scientific technology	Pneumotachograph, pressure to flow conversion technique (Lilly Type Pneumotachograph)	Pneumotachograph, pressure to flow conversion technique (Lilly Type Pneumotachograph)	Identical	Identical
User	Physicians in the office or hospital	Physicians in the office or hospital	Identical	Identical
Components	Laptop	Main Unit	Identical to SpiroSphere (K173937)	Identical to SpiroSphere (K173937)
	Sensor Unit	Sensor Unit	Identical	Identical
	ERT PT	ERT PT	Identical	Identical
Screen Display	Depends on used Laptop	162 x 122 mm	Identical to SpiroSphere (K173937)	Identical to SpiroSphere (K173937)
Interface	Bluetooth USB Wifi/Ethernet	Bluetooth USB Wifi/Ethernet 3G	Identical to SpiroSphere (K173937)	Identical to SpiroSphere (K173937)
Energy type	Li-Ion Battery and Power Supply	Li-Ion Battery and Power Supply	Identical	Identical

ECG Function Comparison			
	Predicate Device MasterScope (K202754)	**Subject Device**	
		SpiroSphere ECG	**CardioSphere**
Intended Use / Indications for Use	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.	The SpiroSphere is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older. With the option ECG, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use. A qualified physician has to reassess all ECG measurements. An interpretation by SpiroSphere ECG is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the SpiroSphere 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	With the CardioSphere, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use. A qualified physician has to reassess all ECG measurements. An interpretation by CardioSphere is only significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the CardioSphere 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 CardioSphere is not intended for

		statements. The SpiroSphere ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The minimum age for ECG application is 4 years. It can be used by physicians in the office or hospital.	use in an EMS environment (Emergency Medical Services Environment). The minimum age for ECG application is 4 years. It can be used by physicians in the office or hospital.
Patient population	patients age 4 years and older	patients age 4 years and older	patients age 4 years and older
Sampling Rate	1000 Hz	500 Hz	500 Hz
Evaluation algorithm	Hannover ECG System (HES)	Identical	Identical
Interpretation algorithm (ECG)	Hannover ECG System (HES)	Identical	Identical
Data output	Recorded and displayed on screen or printed	Identical	Identical
ECG parameter	Heart rate [bpm] RR interval [ms] P wave duration [ms] PR interval [ms] QRS duration [ms] QT interval [ms] Corrected QT (Friderica) [ms] Corrected QT (Bazett) [ms] P wave onset [ms] P wave end [ms] QRS interval onset [ms] QRS interval end [ms] T wave end [ms] QRS axis [degree] P wave axis [degree] T wave axis [degree]	Identical	Identical
Records	Under resting conditions	Identical	Identical
Electrodes	Standards ECG electrodes	Identical	Identical
Lead set-up / location	Standard 12 lead ECG lead set-up	Identical	Identical
Connection of the electrodes	4 mm snap, gilded	Identical	Identical

Electrode type	Standard single use ECG electrodes	Identical	Identical
Technology of ECG signal	Impedance measurement	Identical	Identical
Power supply	5V DC via USB interface	1x AA Alkaline (professional or rechargeable) battery or rechargeable NiMH battery	1x AA Alkaline (professional or rechargeable) battery or rechargeable NiMH battery
Data transmission	USB	Bluetooth 2.1+EDR Protocol: SPP.	Bluetooth 2.1+EDR Protocol: SPP.

ECG Amplifier Comparison

	Reference Device COR12 (K183369)	**Subject Device**	
		SpiroSphere ECG	**CardioSphere**
Intended Use / Indications for Use	The COR12 ECG is intended for measuring the surface electrocardiogram (ECG) of a patient. The acquired ECG can be recorded and displayed on a screen or printed on paper. The COR12 ECG can be used for applications in patients age 4 years and older and a weight of 20 kg or higher. The COR12 ECG is intended to be used for routine ECG collection, recording both under resting and stress conditions. The measurement is performed by trained healthcare professionals under the direction of a physician in healthcare facilities (e.g. the doctor's office or hospital).	The SpiroSphere is a compact device to measure inspiratory and expiratory lung function parameters in adults and children aged 4 years and older. With the option ECG, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use. A qualified physician has to reassess all ECG measurements. An interpretation by SpiroSphere ECG is only significant if it is considered in	With the CardioSphere, electrocardiographic measurements can be made under resting conditions. For this purpose a 12-channel surface electrocardiogram can be measured and recorded. The acquired ECG can be displayed on the screen or printed on paper. The interpretation software is intended to support the physician in evaluation of the resting ECG in terms of morphology and rhythm. Automatic interpretation of the ECG is not possible for pediatric subjects with an age below 16 years and for pacemaker subjects. It is not intended for intra-cardial use. A qualified physician has to reassess all ECG measurements. An interpretation by CardioSphere is only

		connection with other clinical findings. ECG interpretation statements made by the SpiroSphere 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 SpiroSphere ECG is not intended for use in an EMS environment (Emergency Medical Services Environment). The minimum age for ECG application is 4 years. It can be used by physicians in the office or hospital.	significant if it is considered in connection with other clinical findings. ECG interpretation statements made by the CardioSphere 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 CardioSphere is not intended for use in an EMS environment (Emergency Medical Services Environment). The minimum age for ECG application is 4 years. It can be used by physicians in the office or hospital.
Patient population	patients age 4 years and older and a weight of 20 kg or higher	patients age 4 years and older	patients age 4 years and older
Data output	Recorded and displayed on screen or printed	Identical	Identical
Records	Under resting and stress conditions	Under resting conditions	Under resting conditions
Dimensions W x H x D	8.0 x 9.3 x 2.1 cm (3.3 x 3.7 x 0.8 in)	Identical	Identical
Weight (without battery)	200 g (0.4 lbs)	Identical	Identical
12-channel Surface ECG Recording	Yes	Identical	Identical
Electrodes	Standard ECG electrodes	Identical	Identical
Connection of the electrodes	4 mm snap, gilded	Identical	Identical
Technology of ECG signal	Impedance measurement	Identical	Identical

Resolution / Amplitude quantisation	1.94µV/bit ECG	Identical	Identical
Filter	Bandpass 0.05 Hz – 150 Hz No line filter (50 Hz / 60 Hz)	Identical	Identical
Pacemaker detection	4000 Hz	Identical	Identical
Temperature range operation	T = 10 – 37 °C	Identical	Identical
Ambient pressure range operation	700 to 1060 hPa (525 to 795 mmHg)	Identical	Identical
Humidity (operation, storage, transport)	5 – 95% RH (not condensing)	Identical	Identical
Power supply	1x AA Alkaline (professional or rechargeable) battery or rechargeable NiMH battery	Identical	Identical
Runtime	>5h with AA battery >8h with rechargeable NiMH battery (2850 mAh)	Identical	Identical
Classification according to 60601-1 **-Protection type against electric shock** **-Protection level against electric shock**	Device with internal power supply Type CF	Identical	Identical
Recovery Time after defibrillation	< 8 seconds	Identical	Identical
Electromagnetic compatibility (EMC) according to 60601-1-2 and 60601-2-25 **- Emission** **- Immunity**	CISPR 11 Class B IEC 61000-4 parts 2, 3, 6, 8	Identical	Identical
Data transmission	Bluetooth 2.1+EDR Protocol: SPP.	Identical	Identical

17 Comparison Summary

Intended Use

The intended use of the Subject Device is the same as for the Predicate Device.

Technological Characteristics

The Predicate Device MasterScope (K202754) and the Reference Devices SpiroSphere (K173937) and COR12 (K183369) are presently in commercial distribution globally including in the United States of America.

The Subject Device uses the same fundamental scientific technology as the Reference Devices and is substantially equivalent in function and application to the Predicate Device.

Biocompatibility

No new biocompatibility testing has been conducted, as the biocompatibility testing for the Reference Devices remains appropriate for this submission.

Differences

- The Subject Device consists of a Main Unit for display and a wireless ECG amplifier for measurement.
- The Subject Device provides a high resolution, color touch screen instead of a high-resolution graphical LCD touch screen
- The Subject Device provides an additional 3G interface to enable communication.

18 Summary of Device Testing

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

- The device was developed and tested according to GMP Standard Operating Procedures for Medical Devices.
- Software verification and validation was conducted in accordance with IEC 62304 Ed.1.1:2015.
- Risk analysis of the Subject Device was performed according to ISO 14971:2019.
- Tests were performed to confirm that the Subject Device spirometry function 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 and IEC 60601-2-25:2011 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.
- The FDA guidance “Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices” from 2016 was considered.
- Human Factors/Usability Engineering validation according to IEC 62366-1: 2015 and the FDA Guidance “Applying Human Factors and Usability Engineering to Medical Devices” from 2016
- The FDA Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” from 2014 and the Draft Guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices” from 2018 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.

19 Conclusion

Based on the intended use of the SpiroSphere / SpiroSphere ECG / CardioSphere and the results of the electrical safety testing and performance testing provided in the 510(k), the Subject Device has been found to be substantially equivalent to the Predicate Device Masterscope (K202754).

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Subject Device should perform as intended in the specified use conditions.

eResearchTechnology GmbH contends that the SpiroSphere / SpiroSphere ECG / CardioSphere is substantially equivalent to the current legally marketed device MasterScope (K202754). The Subject Device does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.