December 14, 2018

Cardio-Phoenix Inc.
Marc Bisnaire
President
44 Rosemead Close
Markham, L3R 3Z3 Canada

Re: K182790
Trade/Device Name: Cardio-TriTest v6.5
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DXR, DQC
Dated: September 27, 2018
Received: October 1, 2018

Dear Marc Bisnaire:

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,

for Jessica E. Paulsen -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*

K182790

Device Name
Cardio-TriTest v6.5

Indications for Use *(Describe)*

The intended use of the device is to acquire and record the 3 different types of heart bio-signals (ECG, PCG, and MCG) and combine the results into a contiguous presentation as an aid to diagnostic interpretation by a Physician in a clinical setting.

The indication for use is as…
a. a Standard 12 Lead Diagnostic ECG
b. an aid to identify events in the cardiac cycle
c. an aid to detect S1 & S2 hearts sounds and murmurs.

Any diagnostic interpretation is only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

The Cardio-TriTest is on a prescription basis by a Certified Medical Practitioner.

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.

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Chapter 8

510(k) Summary

Cardio-TriTest v6.5

510(k) Summary

The assigned 510(k) number is: K182790

Submitter of 510(k): Cardio-Phoenix Inc.
44 Rosemead Close
Markham, L3R 3Z3
Canada
Phone: 416-595-0795
Email: marc.bisnaire@uvaresearch.com

Contact person: Marc Bisnaire

Date of summary: 27th September 2018

Trade/Proprietary name: **Cardio-TriTest™**

Classification name: **EPMCG v6.5**

Classification: DPS – Electrocardiograph
DXR – Ballistocardiograph
DQC – Phonocardiograph

Product codes: DPS
DXR
DQC

The following device classifications apply to this device:

Name	Class	CFR
Electrocardiograph	II.	870.2340
Ballistocardiograph	II.	870.2320
Phonocardiograph	I.	870.2390

Classification panel: Cardiovascular

Legally marketed predicate devices:

- Cardio-TriTest v5.5 (k143432)

Device Description

The Cardio-TriTest v6.5 (CTT) is three devices in one; combining a 12-Lead Electrocardiograph (ECG), a 4 Lead Phonocardiograph and a 4 lead Mechanocardiograph. The device will acquire all three types of bio-signals during the same non-invasive test procedure. The three types of signals are synchronized and outputted on the same timeline making it easier for general practitioners to visually determine a patient's current heart health.

The ECG component is a Standard 12-Lead ECG, conformant with EN IEC 60601-2-25 standards.

The CTT v6.5 device uses approved Standard 12-Lead FDA/CE cables.

The CTT includes 4 Kombi-Sensors that include combine PCG/MCG functionality.

The PCG component consists of 4 electronic stethoscopes into one Phono recording device.

PCG sensors are equipped with diaphragms and non-chill rings.

The MCG component consists of 4 MCG recording devices integrated into the Kombi-Sensor housing (PCG and MCG in same Sensor Housing).

The PCG and MCG signal verification can be found in **Annex E - Signal Testing**.

The PCG and MCG sensors are housed in common sensor housing, Kombi-Sensor, this allows the Kombi-sensor of being positioned/located in one of the 4 standard auscultation points on the thoracic wall.

The combined PCG/MCG sensors record their signals when positioned on the four primary auscultation points on the thoracic wall.

Intended use:

The Intended Use of the Cardio-TriTest™ is to provide the GP with three different types of non-invasive heart bio-signals as an aid to the Physician in making a broader and more complete diagnosis of cardiovascular health.

Indication for use

The intended use of the device is to acquire and record the 3 different types of heart bio-signals (ECG, PCG, and MCG) and combine the results into a contiguous presentation as an aid to diagnostic interpretation by a Physician in a clinical setting.

The indication for use is as…

a. a Standard 12 Lead Diagnostic ECG

b. an aid to identify events in the cardiac cycle

c. an aid to detect S1 & S2 hearts sounds and murmurs.

Any diagnostic interpretation is only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

The Cardio-TriTest is on a prescription basis by a Certified Medical Practitioner

Intended population

Not intended for use in pediatrics.

Not intended for patients in the intensive care units.

Males and females greater than or equal to 20 years of age.

Technological characteristics and substantial equivalence:

The Cardio-TriTest (CTT) is a 3-in-1 device. It combines the functionality of an Electrocardiograph (ECG), a Phonocardiograph (PCG) and Mechanocardiograph (MCG) device into 1 device.

The value of the CTT is that it synchronizes the 3 different types of bio-signals recorded by each functional aspect of the device and visually correlates them for combined diagnostic purposes.

The technical characteristics of each functional device are either conformant to FDA recognized standards in the case of the ECG functionality or substantially equivalent to their corresponding FDA cleared predicate device for the PCG and MCG functionality.

Safety:

Being a 3-in-1 device, the safety of the device meets the Standard as per IEC 60601-1, in accordance with the standards set in EN IEC 60601-2-25 for Diagnostic ECG and applies equally to the two other functional aspects of the device.

In accordance with FDA guidelines, the ECG component is conformant with EN IEC 60601-2-25 (2015) Diagnostic Electrocardiographs (ECG).

The MCG functionality, acquires and records the mechanical vibrational waveforms produced by the hearts constructions and transmitted to the chest wall.

The PCG functionality, acquires and records the acoustic waveforms produced by the heart.

The Cardio-TriTest v6.5 (CTT) device and the predicate device listed above are indicated for use in the clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. They are not intended as a sole means of diagnosis. The interpretations of heart signals offered by CTT are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

Technological characteristics comparison table:

Features and functions	Cardio-TriTest v5.5	Cardio TriTest v6.5
Device Type	**ECG/PCG/ MCG(BCG)**	**ECG/PCG/ MCG(BCG)**
Software		
Test stored as individual files	YES	Same
Save tests	YES	Same
File retrieval	From Hard drive	Same
Operating system	Windows 7, Windows 8.x (32 or 64bit)	Windows 10 (preferred); also, Windows 7 and 8 (32 or 64bit)
PC-based software	YES	Same
Printing	YES in .pdf	Same
Networked	NO	Same
Modem data transfer	NO	Same
Display sounds in time and frequency domain	YES - in time domain	Same
Recording test		
Saving signals just of	YES	Same

acceptable quality		
Reporting errors during recording	YES – written prompt	Same
Indication of the failure cause and suggested corrective action	YES	Same
Re-recording ability	YES	Same
Synchronized Stacked Display	Yes (ECG & PCG & MCG)	Same
Rhythm Strip	YES	Same
ECG	YES, 12-lead ECG	Same
X axis MCG	YES	Same
Y axis MCG	YES	Same
Z axis MCG	YES	Same
XYZ combined	YES	Same
Preset recording time	User configurable 30, 60, 120, 180, 300 seconds	60 seconds x 3 recordings
Data resolution	24bit	Same
Sampling rate	1000 Hz ECG 4000 Hz PCG 1000 Hz MCG	4000 Hz analog ECG, 4000 Hz analog PCG 4000Hz analog MCG
Output data format	Zipped binary	Same
Acoustic sensor	Electronic stethoscope	Same
Number of sensors (PCG-MCG)	4	Same
Waveform review		
Waveform markers	NO	Same

	Not required for Intended Use	
Zoom option	YES	Same
Signal averaging	NO	Same
Digital filtering	YES 4 kind of ECG filter, 1 PCG, 1 MCG	Same
Heart sound analysis	NO	Same
Number of display panels	3	Same
Identifying presented specific heart sounds	S1, S2	Same
Graphically displays heart wave intensity, timing and location	NO	Same
Spectrogram view	NO	Same
Wavelet view	NO	Same
Hardware		
Portable unit	Transportable unit	Same
Battery power	NO	Same
Tri-axial accelerometer	YES	Same
ECG Lead Wires	YES	Same
Data transmitting	USB 2.0	USB 3.0
PC connection – input type	USB port	Same
Display requirement	1024x600 graphic display or better	Same
Connectivity	USB 2.0 +	USB 3.0 (USB 2.0)

Bluetooth	NO	Same
Power supply	5v	Same

Any differences in technical characteristics, such as differences in Windows OS systems, type and number of sensors, sampling frequency rate, preset recording time, data transmission type, power supply type, recording format, auscultation frequency range, sound comparing opportunity, number of display panels, PC connection type do not raise any significant concern with respect to the safety or on the effectiveness of the operating results.

Safety and performance:

The Cardio-TriTest is a 3-in-1 device. The criteria for safety is governed best by the ECG functionality which is subject to FDA recognized safety standard set out in IEC 60601-1. The Cardio-TriTest device has passed all the required safety standards and has also been subjected to extensive safety and performance testing.

Final testing for the device included various performance tests, including software validation corresponding to each functional aspect of the device, to ensure that all safety and performance specifications were met.

The Cardio-TriTest device has also been tested to assure compliance to the requirement of various published standards including the following:

Standards covered:

- IEC 60601-1:2012 ed. 3, Medical electrical equipment – Part 1: General requirements for safety
- EN IEC 60601-1-2:2015 ed.4, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- EN IEC 60601-2-25:2015 ed. 2, Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-1-6:2010, ed. 3, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

Standards referenced:

- AAMI/ANSI EC53:2013, ECG trunk cables and patient leadwires (cardiovascular)
- ISO 13485:20016, Quality management systems – Requirements for regulatory purposes
- ISO 14971:2007, Medical devices – Application of risk management to medical devices

The modifications made have not impacted the safety and effectiveness of the device.

The intended use is the same.

Both proposed device and predicate device comply with the same standards and the relevant tests demonstrate the safety and effectiveness.

Conclusion:

Based upon the predicate's corresponding indications for use, their technological characteristics and their safety and performance testing, the Cardio-TriTest v6.5 has been shown to be substantially equivalent to the corresponding above listed legally marketed predicate device under the Federal Food, Drug, and Cosmetic Act.