February 28, 2021

Qardio Inc.
Rosario Iannella
Chief Technology Officer
345 California Street, Suite 600 & 700
San Francisco, California 94104

Re: K201644
Trade/Device Name: QardioCore
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: June 15, 2020
Received: June 17, 2020

Dear Rosario Iannella:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201644

Device Name
QardioCore ECG ambulatory monitoring device

Indications for Use *(Describe)*
The QardioCore ECG ambulatory monitoring device is intended to capture, store, transmit, and display ECG information for recording periods of up to 24-hours in a single session. It is indicated for use on adult patients who may be asymptomatic or who meet clinical indications to perform an ECG-Holter monitor exam.
The QardioCore ECG monitor is a prescription-only device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.

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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510(k) Summary (per 21 CFR 807.92)

Submitter's information

Name: Qardio, Inc.
Address: 345 California Street, Suite 600 & 700, San Francisco, CA, 94104, USA
Contact Person: Rosario Iannella, Chief Technology Officer
Phone number: (415) 670-9613
Date of preparation: January 22, 2021

Device Information

Trade name: QardioCore
Device name: QardioCore ECG Monitor
Device model: C100
Classification name: Medical Magnetic Tape Recorder (21 CFR 870.2800)
Common name: Electrocardiograph
Classification: 2
Specialty: Cardiovascular
Product code: DSH

Predicate device

iRhythm Technologies, Inc., Zio Patch, K121319

Reference device (Clinical study)

ELA Medical, Inc., Spiderview Holter ECG recorder, K032466

Device Description and Test Principle

The QardioCore ECG ambulatory monitoring device is intended to capture, store, transmit, and display ECG information for recording periods of up to 24-hours in a single session. It is indicated for use on adult patients who may be asymptomatic or who meet clinical indications to perform an ECG-Holter monitor exam.

The QardioCore ECG monitor is a prescription-only device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.

The QardioCore ECG Monitor is composed of six main components: i) the QardioCore sensor with Bluetooth technology, ii) a chest strap that allows fitting of QardioCore sensor, iii) a USB charging cable, iv) the Qardio App (can be downloaded and installed from the respective App store) and runs on any iOS device with iOS version 10.0 or later, v) the cloud based server where the Qardio App stores and retrieves data, and vi) the ECG Viewer which provides a web interface to the doctor to view the data sent by the iPhone application.

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The QardioCore device is a wearable device that captures information through a single-channel ECG. The data is then encrypted and transmitted via Bluetooth Low Energy to the Qardio App, installed on a compatible mobile platform. The QardioCore is supplied with chest straps accommodating chest sizes ranging from 27-5 to 43 inches. An optional XL chest strap is available from 41.7 to 59.8 inches. The device is provided with a USB Type-A cable to charge the device.

The Qardio App (which can be installed from the user's respective app store), can transmit the data, via Wi-Fi or standard data mobile telephony, to Qardio cloud based server for storage processing and transmission to an expert medical professional.

The ECG Viewer application provides a web interface to the doctor to view the ECG data collected from the iPhone Application. All data that a patient accumulates using the QardioCore device is stored in the central server. The ECG Viewer provides the doctor with ECG data and Heart Rate (BPM), which a doctor can use as additional information for forming a medical diagnosis. The doctor is able to see both the ECG data and Heart Rate (BPM) as soon as the data becomes available in the central server provided that the patient accepts the doctor's request for access. The device does not include automated analysis except for heart rate calculation. QardioCore is not suitable for physicians who need to perform ECG diagnoses such as myocardial ischemia, left ventricular hypertrophy or specific bundle branch blocks that require multiple and precise electrode placement and consistent wave amplitude.

Indications for use

The QardioCore ECG ambulatory monitoring device is intended to capture, store, transmit, and display ECG information for recording periods of up to 24-hours in a single session. It is indicated for use on adult patients who may be asymptomatic or who meet clinical indications to perform an ECG-Holter monitor exam.

The QardioCore ECG monitor is a prescription-only device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.

Comparison Tables

Table 5.A Comparison of applied regulations

	Subject Device	Predicate Device	Reference Device
510(k) Number	K201644	K121319	K032466
Applicant	Qardio, Inc.	iRhythm Technologies, Inc.	ELA Medical, Inc.
Device Name	QardioCore ECG Monitor	Zio Patch	Spider View Holter ECG recorder
Classification Regulation	21 CFR 870.2800	21 CFR 870.2800	21 CFR 870.2800

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Product Code	DSH	DSH	MWJ
Prescription Use Only	Yes	Yes	Yes

Table 5.B Comparison of IFU

Device	Indications For Use
Subject device *QardioCore, C100*	*The QardioCore ECG ambulatory monitoring device is intended to capture, store, transmit, and display ECG information for recording periods of up to 24-hours in a single session. It is indicated for use on adult patients who may be asymptomatic or who meet clinical indications to perform an ECG-Holter monitor exam.* *The QardioCore ECG monitor is a prescription-only device, and the reported information is provided for review by a physician who will render a diagnosis based on clinical judgment and experience.*
Predicate device *Zio® Patch* (K121319)	*The Zio® Patch is a prescription-only, single-patient-use, continuously recording EGG monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.*

As shown above, the indications for use for the QardioCore ECG Monitor are similar to the primary predicate device in that they are both intended for adult patients, are not intended to be diagnostic devices, are prescription-only devices, and they are intended to provide additional information to healthcare professionals.

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Table 5.C Comparison of performance

	Subject Device	Predicate Device	Reference Device
Wear Time	Up to 24 hours for a single session and can be used for multiple recording periods allowing long-term monitoring and evaluation.	Up to 14 days	24-96 hours (4 days)
Memory Capacity	12 hours when not connected to an iOS device. Once connected, memory capacity is essentially unlimited due to transmission to remote memory.	Up to 14 days	16, 32 or 64 MB
Recording Format	Continuous	Continuous	Unknown
Ambulatory Use	Yes	Yes	Unknown
Sterilization	Non-Sterile	Non-sterile	Unknown
System Architecture	Requires an external device to constitute a complete electrocardiograph system	Requires an external device to constitute a complete electrocardiograph system	Unknown
Patient Interface	Integrated electrodes placed on patient's chest	Integrated electrodes placed on patient's chest	Unknown
Display and User Interaction	Data is displayed via the mobile app.	Data is displayed via a mobile app or website.	Graphic LCD
Battery Type	Lithium polymer cell	Lithium polymer cell	1 AA 1.5V battery or 1 AA 1.2V NiMH rechargeable battery
Activity Sensor	Yes	None	Unknown
Heart Rate (HR) Measurement	Yes	Yes	Unknown
Data Telemetry	Yes Bluetooth, Cellular network / Wi-Fi	None	Unknown
Telemetry Device	Commercial smartphone/tablet	N/A	Unknown
Dimensions	7.3 x 3.4 x 0.4 in (185 x 87 x 9mm)	4.79 x 2.07 x 0.42 in (123 x 53 x 10.7mm)	3.82 x 2.13 x 0.91 in (97 x 54 x 23 mm)
Weight	0.287 lbs. (130g)	0.0749 lbs. (34g)	110g with batteries and flash card
Operating conditions	-4 to 104° F (-20 to 40° C) for discharging 25 – 90% RH (non-condensing)	36 to 104° F (2 to 40° C)	Unknown
	32 to 104° F (0 to 40 0C) For charging	Unknown	

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	Subject Device	Predicate Device	Reference Device
Operating Altitude	Up to 9,842 ft (3,000 m)	-1,000 to 10,000 ft (-305 to 3,048 m)	Unknown
Storage Conditions	-4 to 104° F (-20 to 40° C) 45 to 85% RH (non-condensing)	64 to 80° F (18 to 27° C) 10 to 95% RH (non-condensing)	Unknown
Storage Altitude	Up to 9,842 ft (3,000 m)	-1,000 to 14,000 ft (-305 to 4,267 m)	Unknown
Frequency Response	0.05 Hz to 40 Hz	Unknown	0.05 to 25 Hz
Input Impedance	≥ 100 Mohm	≥3 Mohm	**Unknown**
Differential Range	± 5 mV	± 1.65 mV	± 16 mV
A/D Sampling Rate	600 samples / second (600 Hz)	200 samples / second (200Hz)	1000 samples/second (1000 Hz)
Resolution	16 bits	10 bits	15 bits
Common Mode Rejection Ratio (CMRR)	120 dB Conforming to IEC 60601-2-47 Section 201.12.4.4.103	≧60 dB Conforming to IEC 60601-2-47 Section 201.12.4.4.103	**Unknown**

Substantial Equivalence Discussions

The subject device is similar to the predicate device and reference device in terms of technical specifications and performance. The minor differences in the recording characteristics, data transmission characteristics, physical characteristics and environmental specifications do not raise new questions of safety and effectiveness. Performance testing is described below and demonstrates that the subject device meets the specifications for its intended use. Clinical testing is described below and demonstrates that the subject device performs as intended and is capable of providing clinically useful ECG information that is comparable to the FDA cleared Zio Patch (K121319).

Non-Clinical Testing in Support of Substantial Equivalence Determination

All necessary performance testing was conducted on the QardioCore to support determination of substantial equivalence to the predicate devices. The results are confirmed by examination and provision of objective evidence that the design output meets the design input requirements in conformance with the following list of international standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012): General requirements for basic safety and essential performance, *FDA recognition number: 19-4*
- IEC 60601-1-2:2014: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, *FDA recognition number: 19-8*

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- IEC 60601-1-11:2015 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment, *FDA recognition number: 19-14*
- IEC 60068-2-64: Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
- IEC 60068-2-27:2008: Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock
- IEC 60601-2-47: 2012 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems, *FDA recognition number: 3-155*
- IEC 62133: 2012: Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications, *FDA recognition number: 19-13*
- UN ST/SG/AC.10/11/Rev.6/Section 38.3, Recommendations on the TRANSPORT OF DANGEROUS GOODS
- EN ISO 10993-1: 2009/AC 2010: Biological evaluation of medical devices – Part 1: Evaluation of testing within a risk management process, *FDA recognition number: 2-220*
- EN ISO 10993-5: 2009: Biological evaluation of medical devices – Part 5: Tests for *in vitro* cytotoxicity, *FDA recognition number: 2-245*
- EN ISO 10993-10: 2010: Biological evaluation of medical devices – Tests for irritation and skin sensitization, *FDA recognition number: 2-174*
- ANSI/AAMI EC57: 2012: Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms, *FDA recognition number: 3-118*

Clinical Testing in Support of Substantial Equivalence Determination

The purpose of the study was to demonstrate the accuracy of the QardioCore ECG Monitor in generating ambulatory ECG signal non-inferior in terms of signal quality to standard ECG parameters provided by a conventional, FDA-cleared, 3-channel ECG-Holter monitor device over a 24-hour recording time. The reference device used in the study is the Spiderview Holter ECG recorder manufactured by ELA Medical, Inc., Plymouth, MN, (K032466).

The study was conducted in a population consistent with the device indications for use. ECGs from the subject and reference devices were collected and analyzed in a blinded fashion at various timepoints representative of realistic device use. Various qualitative and quantitative metrics, including signal quality, relevant ECG waveform amplitude and intervals, artifact burden, and comfort, were measured and analyzed. The data provided demonstrated the substantial equivalence with the predicate device.

Conclusion

Testing results of the electrical safety, EMC, non-clinical performance testing and clinical testing presented in the submission demonstrate that any difference in the technological characteristics does not raise any new issue affecting the safety and effectiveness of the QardioCore device as compared to the predicate devices. Thus, the subject device QardioCore is substantially equivalent to the identified predicate device.