June 15, 2022

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

Re: K220106
Trade/Device Name: QardioArm 2
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 16, 2022
Received: May 16, 2022

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,

LCDR Stephen Browning
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)*
K220106

Device Name
QardioArm 2

Indications for Use *(Describe)*

The QardioArm 2 is a fully automatic, non-invasive, wireless blood pressure monitor intended to measure the systolic and diastolic blood pressures and pulse rate of adult individuals. It utilizes an inflatable cuff that is wrapped around the upper arm. The arm circumference is limited to 8.7 - 18.5 inches (22 - 47 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is not intended to be used as a diagnostic device and users are instructed to contact their physician if hypertensive values are indicated.

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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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the QardioArm 2 is provided below.

1. SUBMITTER

Applicant: Qardio, Inc.
345 California Street, Suite 600 & 700
San Francisco, CA 94104, USA
Phone: (415) 670-9613
Fax: (415) 520-9601

Contact: Rosario Iannella
Chief Technology Officer
compliance@qardio.com

Submission Correspondent: Rosario Iannella
Chief Technology Officer
compliance@qardio.com

Date Prepared: May 5, 2022

2. DEVICE

Device Trade Name:	QardioArm 2
Device Common Name:	Noninvasive blood pressure measurement system
Classification Name	21 CFR 870.1130
Regulatory Class:	Class II
Product Code:	DXN

3. PREDICATE DEVICE

Predicate Device: K140067, QardioArm A100

4. DEVICE DESCRIPTION

The QardioArm 2 is an over-the-counter (OTC) non-invasive blood pressure monitor intended for spot-checking in adults. It uses a detachable inflatable cuff that is wrapped around the upper arm to determine blood pressure based on the oscillometric method. Two cuff sizes are available: standard size for an arm circumference of 8.7 to 14.6 inches or large size for an arm circumference of 14.6 to 18.5 inches.

5. INTENDED USE/INDICATIONS FOR USE

The QardioArm 2 is a fully automatic, non-invasive, wireless blood pressure monitor intended to measure the systolic and diastolic blood pressures and pulse rate of adult individuals. It utilizes an inflatable cuff that is wrapped around the upper arm. The arm circumference is limited to 8.7 - 18.5 inches (22 – 47 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is not intended to be used as a diagnostic device and users are instructed to contact their physician if hypertensive values are indicated.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

Subject Device	Predicate Device [K140067]
The QardioArm 2 is a fully automatic, non-invasive, wireless blood pressure monitor intended to measure the systolic and diastolic blood pressures and pulse rate of adult individuals. It utilizes an inflatable cuff that is wrapped around the upper arm. The cuff circumference is limited to 8.7-18.5 inches (22-47 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is not intended to be used as a diagnostic device and users are instructed to contact their physician if hypertensive values are indicated.	QardioArm, model A100 is a fully automatic, non-invasive, wireless blood pressure monitor. QardioArm, model A100 is a blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual. QardioArm, model A100 utilizes an inflatable cuff that is wrapped around the upper arm. This device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated. The cuff circumference is limited to 22 cm-37 cm (8.7 in - 14.6 in).

The indications for use of the QardioArm 2 are very similar to the predicate device in that they are both fully automatic, oscillometric devices intended for measuring blood pressure and pulse rate in adult patients. The devices are both available OTC and neither device is intended to be used to provide a diagnosis. The differences in the indications are limited to larger cuff sizes being available for the QardioArm 2, and an explicit reference to the ability of the device to detect the appearance of irregular heartbeats during measurement (this feature was also present in the predicate device). These minor differences do not impact the fundamental intended use of the device, which is to measure blood pressure and pulse rate.

Technological Comparisons

The table below compares the key technological features of the subject devices to the predicate device (QardioArm A100, K140067).

Table 1: Technological Comparison

Comparison item	Predicate device	Proposed device
510(k) Number	K140067	To be assigned

Comparison item	Predicate device	Proposed device
Applicant	Qardio, Inc.	Qardio, Inc
Device Name	QardioArm A100	QardioArm 2
Classification Regulation	21 CFR 870.1130 Class II	21 CFR 870.1130 Class II
Product Code	DXN	DXN
Rx or OTC	OTC	OTC
Measurement method	Oscillometric	Oscillometric
Data collected	Systolic and Diastolic Blood Pressure Pulse	Systolic and Diastolic Blood Pressure Pulse
Measurement range	Systolic measurement range: 60~250mmHg Diastolic measurement range: 40~180mmHg Pulse measurement range: 40~200 beats/minute for pulse	Systolic measurement range: 60~250mmHg Diastolic measurement range: 40~180mmHg Pulse measurement range: 40~200 beats per minute
Measurement Resolution	1 mmHg for blood pressure. 1 beat/min for pulse.	1 mmHg for blood pressure. 1 beat/min for pulse.
Accuracy	+/-3mmHg or 2% reading for blood pressure. +/-5% for pulse.	+/-3mmHg or 2% reading for blood pressure. +/-5% for pulse.
Pressure deflation	Automatic Inflation/ Deflation	Automatic Inflation/ Deflation
Wireless communication	Bluetooth 4.0	Bluetooth 5.0
Display	Display the measurement result on smart Phones (iOS and Android)	Display the measurement result on smart Phones (iOS and Android)
Cuff circumference	8.7 in – 14.6 in diameter (22 cm – 37 cm diameter), not detachable	22~37cm M, detachable 37~47cm XL, detachable
Operating temperature & humidity	50~104°F (10~40°C) temperature, 15~90% relative maximum humidity,	41~104°F (5~40°C) temperature, 15~90% relative maximum humidity,
	Atmospheric pressure 86 kpa~106 kpa, maximum altitude: 2000m (6561 ft).	Atmospheric pressure 70 kpa~106 kpa, maximum altitude: 3000m (9,842 ft).

Comparison item	Predicate device	Proposed device
Storage temperature & humidity	-13~158°F (-25~70°C) temperature, 10~95% relative maximum humidity,	-13~158°F (-25~70°C) temperature, 10~95% relative maximum humidity,
	Atmospheric pressure 86 kpa~106 kpa, maximum altitude: 2000m (6561 ft).	Atmospheric pressure 70 kpa~106 kpa, maximum altitude: 3000m (9,842 ft).
Power	4 Alkaline 1.5V batteries (AAA)	Rechargeable Lithium-ion Battery (3.7V/1000mAh)
Weight	0.68 lb (310 g) including batteries	0.63 lb (290 g) including batteries device with M cuff 0.67 lb (305g) including the battery with XL cuff
Device Dimensions	5.5 x 2.7 x 1.5 in (140 x 68 x 38 mm) when closed.	5.5 x 2.7 x 1.5 in (140 x 68 x 38 mm) when closed with standard cuff.
		5.5 x 2.7 x 1.7 in (140 x 70 x 45mm) when closed with XL cuff.

7. PERFORMANCE DATA

Biocompatibility Testing

The subject device in its final finished form is identical to QardioArm A100, cleared in K140067, in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).Therefore, no additional biocompatibility information is required to establish substantial equivalence.

Electrical safety and electromagnetic compatibility (EMC)

The QardioArm 2 was tested in accordance with IEC 60601-1:2005 (3rd ed) + CORR. 1:2006 + CORR.2:2007+A1:2012 *Medical electrical equipment: Part 1: General requirements for basic safety and essential performance* including US deviations, with the exception of Clause 11.7 regarding biocompatibility. The device passed all tests, including the US deviations.

The QardioArm 2 was tested in accordance with the FDA-recognized standard IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests*. The QardioArm 2 passed all tests.

The QardioArm 2 was tested in accordance with the FDA-recognized standard, IEC 62133-2:2017, *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 – Part 2: Lithium systems*, and found to comply with all relevant sections.

The QardioArm 2 underwent wireless coexistence testing in accordance with AAMI TIR69:2017 and ANSI C63.27:2017. All tests passed.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

Bench Testing

The following bench testing was performed to demonstrate substantial equivalence: :

- Home Healthcare Environment Testing. The QardioArm 2 was tested in accordance with 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*. The device passed all tests.
- Automated Non-Invasive Sphygmomanometer Testing. The QardioArm 2 was testing in accordance with IEC 80601-2-30:2018, *Medical electrical equipment – Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*. The device passed all tests.
- Summative Human factors testing was performed in accordance with the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". The QardioArm 2 was found to be safe and effective for its intended users, uses, and use environments

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

A prospective, single arm paired comparison study designed in accordance with ISO 81060-2:*2018 Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type* was conducted to demonstrate the performance of the QardioArm 2 on adult subjects. In the study the QardioArm 2 blood pressure monitor was compared to the Reference sphygmomanometer via a same arm sequential method with dual auscultators. The primary study endpoints and statistical analysis plan were established in accordance with ISO 81060-2 and FDA's requirements for 510(k) submissions for oscillometric blood pressure devices. The study

enrolled 86 subjects who met the inclusion requirements of 81060-2. The device met all the requirements of the standard.

8. CONCLUSION

The QardioArm 2 has the same intended use as the predicate device, namely, to measure blood pressure and pulse rate in adult users. Performance testing demonstrates that the QardioArm 2 meets the specifications for its intended use, complies with relevant standards, and performs equivalently to the predicate device. Therefore, the QardioArm 2 can be found substantially equivalent to the predicate device.