JUN 18 2014

Summary of Safety and Effectiveness

(According to 21 CFR 807.92)

510(k) Summary for _____

Submitter's information

Name	:	Qardio, Inc.
Address	:	340 S Lemon Ave #1104F, Walnut, CA 91789, USA
Phone number	:	+1-(415) 670.9668
Fax number	:	+1-(415) 520.9601

Manufacturer's name

Name	:	YA HORNG ELECTRONIC CO., LTD.
Address	:	No.35, Shalun, Anding Dist., Tainan City 745, Taiwan (R.O.C.)
FDA Registration	:	#3001147827
510k Contact person	:	Dr. Jen, Ke-Min Tel: +886-3-5208829 Fax:+886-3-5209783 Email: ceirs.jen@msa.hinet.net
Date of preparation	:	December 29, 2013

Device name

Trade name	:	QardioArm
Device name	:	QardioArm, model A100
Common name	:	Blood Pressure Monitor

Classification

Classification name	:	Non-Invasive Blood Pressure Monitoring System
Regulation number	:	21CFR Section 870.1130
Class	:	II (Two) performance standards
Specialty	:	Cardiovascular
Product code	:	DXN

Predicate devices

- KD-936 Fully Automatic Wireless Blood Pressure Monitor (K120672)
- Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W (K121025)

Device Information

Device description : QardioArm, model A100 measures both systolic and diastolic blood pressure and heart pulse rate via a standard oscillometric method. The oscillometric method senses the vibrating signal via the closed air pipe system and utilizes a microcomputer to automatically sense the characteristics of the pulse signal. Unlike with the traditional measuring method, based on the Korotkov sound, with the oscillometric method the use of a stethoscope is not required. Through simple calculations, this method provides accurate blood pressure readings: the systolic pressure is defined as the blood pressure when the cuff pressure oscillating amplitude begins to increase, while the diastolic blood pressure is defined as the pressure when the cuff pressure oscillating amplitude stops decreasing.

The device includes a plastic enclosure and an integrated wrap-around cuff, and it requires an external device (e.g. a smartphone) to display results and perform user interaction.

Indication for use : 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 22cm-37cm (8.7in -14.6in)

Test Summary:

1. ELECTRIC SAFETY, EMC and FCC test reports,

General safety	IEC 60601-1:2005	PASS
	EN 1060-1:2002, EN 1060-3:2005	PASS
EMC conformity	IEC 60601-1-2: 2007	PASS
FCC conformity	ANSI C63.4	PASS

2. WOVEN COTTON SHEETING:

(Same as the predicate devices: YA HORNG Upper Arm Blood Pressure Monitor, Bluetooth Transmission; Type: BP700W, K121025)

Uses the 510K Blood-Pressure Cuff: YA HORNG Blood-Pressure Cuff (K051539).

3. PERFORMANCE & CLINICAL TEST

ANSI/AAMI ISO 81060-2:2009

EN 1060-4:2004

Comparison with predicate device and conclusion

Comparison item	Proposed device	Predicate device	Predicate device
Applicant	Qardio, Inc.	YA HORNG Electronic Co., Ltd.	Andon Health Co., Ltd.
Trade name	QardioArm	YA HORNG Upper Arm Blood Pressure Monitor, Bluetooth Transmission	iHealth BP5 Fully Automatic Arm Cuff Wireless Blood Pressure Dock
Model name	A100	BP700W	KD-936
510K number	New listing	K121025	K120672
Technological characteristics	Oscillometric method	Oscillometric method	Oscillometric method
Measuring method	Oscillometric method, automatic inflation and measurement	Oscillometric method, automatic inflation and measurement	Oscillometric method, automatic inflation and measurement
Sensor	Semiconductor gauge sensor	Semiconductor gauge sensor	Semiconductor gauge sensor
Rapid air release	By an active electronic control valve	By an active electronic control valve	By an active electronic control valve
Pressure accuracy	Pressure: ±3mmHg or ±2% of readout value	Pressure: ±3mmHg or ±2% of readout value	Pressure: ±3mmHg
Pulse accuracy	±5% of reading value	±5% of reading value	±5% of reading value
System architecture	Requires an external device to constitute a complete blood pressure measurement system	Independent operation	Requires an external device to constitute a complete blood pressure measurement system
Display and user interaction	Requires an external device to display results and perform user interaction	LCD monitor and personal computer	Requires an external device to display results and perform user interaction
Power source	Disposable 4 x AAA alkaline batteries	Disposable 4 x AAA alkaline batteries	Rechargeable batteries (Li-Ion 400 mAh)
Communication:	Wireless, based on Bluetooth V4.0 (Bluetooth Low Energy)	Wireless, based on Bluetooth V2.0	Wireless, based on Bluetooth V3.0 + EDR
Cuff type and size	Upper arm type, size: 22 to 37cm	Upper arm type, size: 23 to 33cm	Upper arm type, size: 22 to 48cm
Operating temp. and humidity	10 to 40°C, 15 to 90% RH, atmospheric 86Kpa to 106kpa, altitude: 2000m	10 to 40°C, 15 to 90% RH, atmospheric 86Kpa to 106kpa, altitude: 2000m	5 to 40°C, < 90 %RH
Storage temp. and humidity	-25 to 70°C, 10 to 95% RH, atmospheric 86Kpa to 106kpa, altitude: 2000m	-25 to 70°C, 10 to 95% RH, atmospheric 86Kpa to 106kpa, altitude: 2000m	-20 to 55°C < 90 %RH

Summary with predicate device and conclusion

The new device, QardioArm, model A100 is substantially equivalent to the KD-936 Fully Automatic Wireless Blood Pressure Monitor (K120672) and the YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W (K121025).

YA HORNG Electronic Co., Ltd. (FDA owner number 9040892) is the manufacturer of the QardioArm, model A100 and the predicate device YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W (K121025). Furthermore, the QardioArm, model A100 and the predicate device YA HORNG Upper Arm Blood Pressure Monitor, model BP-700NW and Bluetooth Transmission BP-700W share the same design specifications.

The intended use and the indications for use of the QardioArm, model A100 as described in its labeling are the same as the two predicate devices and all three devices are intended to be used in the same manner and environments.

The QardioArm, model A100 and the predicate devices are substantially equivalent in the technological characteristics of patient contact materials, performance, biocompatibility function, mechanical safety, standards met, electrical safety, and EMC.

Only the user interface and visual appearance, and the cuff size for the new device and the predicate devices are different. The QardioArm, model A100 and the two predicate devices use Bluetooth technology for wireless communications with an external device. However, QardioArm, model A100 uses Bluetooth V4.0 (Bluetooth Low Energy) to operate with wireless communications with an iPhone, iPod or iPad, while the KD-936 Fully Automatic Wireless Blood Pressure Monitor uses Bluetooth V3.0+EDR to operate with wireless communications with an iPhone, iPod or iPad, and the YA HORNG Upper Arm Blood Pressure Monitor, Bluetooth Transmission BP-700W uses Bluetooth V2.0 to operate with wireless communications with a personal computer.

Thus they are substantially equivalent.

Qardio, Inc. believes this information and the referred documentation to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate products and other products currently in distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 18, 2014

Qardio, Inc.
c/o Dr. Jen, Ke-Min
340 S Lemon Ave #1104F
Walnut, CA 91789
USA

Re: K140067
Trade/Device Names: QardioArm, Model A100
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: May 3, 2014
Received: May 9, 2014

Dear Dr. Jen:

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. 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.

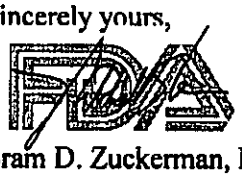
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K140067

Device Name: QardioArm, model A100

- Indications for use:

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 22cm~37cm (8.7in ~14.6in).

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

ConcurrenceofCDRH,OfficeofDeviceEvaluation(ODE)

Date: 2014.06.18 07:30:33 -04'00'