January 10, 2018

Medicomp, Inc.
% Susan Goldstein-Falk
mdi Consultants
55 Northern Blvd
Great Neck, New York 11021

Re: K173170
Trade/Device Name: Epicardia Anywhere
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: December 7, 2017
Received: December 11, 2017

Dear Susan Goldstein-Falk:

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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173170

Device Name
Epicardia Anywhere

Indications for Use *(Describe)*

The Epicardia Anywhere is indicated as a screening tool for patients who require ambulatory ECG monitoring for extended time periods. The system records and analyzes the patient's ECG, and provides various summary reports that detail any clinically-significant events the patient may have had, based on the Epicardia Anywhere classifications. These reports are then reviewed, revised if necessary by a trained operator and then confirmed by a qualified clinician.

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."

510(k) SUMMARY

The assigned 510(k) number is: K173170

1. SUBMITTER'S INFORMATION

Company Name: Medicomp, Inc.

Company Address: 600 Atlantis Rd. Melbourne Florida, 32904, USA

Date Summary Prepared: January 9, 2018

Contact: Mr. Sean Marcus

Medicomp, Inc.
600 Atlantis Road
Melbourne, FL 32904
TEL: 321-676-0010 x2150
E-MAIL: smarcus@medicompinc.com

2. SUBJECT DEVICE IDENTIFICATION

Trade Name: Epicardia Anywhere

Common Name or Classification Name: Arrhythmia Detector and Alarm

CFR Part 870.1025

Product Code: DSI

Device Class: II (two)

3. PREDICATE DEVICE IDENTIFICATION

Trade Name: Epicardia 5000

Common Name or Classification Name: Arrhythmia Detector and Alarm

CFR Part 870.1025

Product Code: DSI

Device Class: II (two)

K090834

4. DEVICE DESCRIPTION

The Epicardia Anywhere System is a screening tool for patients who require ambulatory ECG monitoring for extended time periods. The system records and analyzes the

patient's ECG, and provides various summary reports that detail and clinically-significant events the patient may have had, based on the Epicardia Anywhere classifications. These reports are then reviewed, revised if necessary by a trained operator and then confirmed by a qualified clinician.

5. INDICATIONS FOR USE

The Epicardia Anywhere is indicated as a screening tool for patients who require ambulatory ECG monitoring for extended time periods. The system records and analyzes the patient's ECG, and provides various summary reports that detail any clinically-significant events the patient may have had, based on the Epicardia Anywhere classifications. These reports are then reviewed, revised if necessary by a trained operator and then confirmed by a qualified clinician.

6. COMPARISON OF SUBJECT DEVICE TO PREDICATE DEVICE

The operating system in both the predicate and subject devices remain the same, using a Microsoft Windows based application. The main technological difference between the two devices is the environment in which the server is located.

The predicate device, Epicardia 5000, uses a desktop-based application. The subject device, Epicardia Anywhere, uses the Azure-cloud based server with a core processor. The predicate device, Epicardia 5000, can be client installed on the windows based PC that communicates with a server on the back end. The subject device, Epicardia Anywhere is a web based application that connects to the server on the back end from the PC. Both the subject and predicate devices have a back-end server with a core processor.

Epicardia Anywhere is accessible from across the Internet using popular web browsers. The subject device will retain all major functionality of the predicate device. No new issues of safety or effectiveness are introduced by using this device. This modification remains substantially equivalent and is accounted for in the Device Hazard Analysis.

Below is a comparison chart outlining the similarities and differences between the subject and predicate devices:

	PREDICATE DEVICE Epicardia 5000 K090834	**SUBJECT DEVICE** Epicardia Anywhere	**SUBSTANTIALLY EQUIVELENT**
ECG Analysis	Yes (Diogenes)	Yes (Diogenes)	Identical/SE
User Interface	Personal Computer (Windows)	Personal Computer (Windows)	Identical/SE
PC interface	TCP/IP Trans Telephonic Cellular Direct USB File	TCP/IP Trans Telephonic Cellular Direct USB File	Identical/SE
Operating System	Microsoft Windows	Microsoft Windows	Identical/SE
Location of Server	Desktop	Azure-cloud based	Different/SE
EC38 Type	Type 3	Not Applicable	Different/SE
Unique Patient ID	Limited	Unlimited	Different/SE
Processor	16 BIT	64 BIT	SE
Consecutive ECG (Workflow)	24-Hours to 30-Day	24-Hours to 30-Day	Identical/SE

Comparisons Summary

A. Indications for Use

The Indications for Use is the same, with exception of adding required age designation and prescription notation.

B. Technological Characteristics

The ECG analysis, Diogenes, remains the same. The version of Diogenes in the subject device is the same version of Diogenes in the predicate, Epicardia 5000.

The user interface is the same, the predicate and the subject device applications run on a personal computer. Both the predicate and the subject device are a Microsoft Windows based interface. The predicate device, Epicardia 5000 presents patient data from a workflow perspective, as does the subject device, Epicardia Anywhere.

Both the predicate and the subject device use the same interface options: TCP/IP, Trans-telephonic, Cellular, Direct, USB and file based interfaces.

The operating system in both the predicate and subject device remains the same, using a Microsoft Windows based application. The main technological difference between the two devices is the environment in which the server is located. The predicate device, Epicardia 5000, uses a desktop-based application. The subject device, Epicardia Anywhere, uses the Azure-cloud based server with a core processor.

The EC38 Type is not applicable for Epicardia Anywhere because it is solely a software system. The unique patient ID is changed from limited to unlimited. The server side software is changed from 16 bit to 64 bit. The predicate and subject devices both present consecutive ECG of 24 hours to 30 days in workflow.

The Technological Characteristics are substantially equivalent to the predicate device.

C. Comparison between Subject and Predicate Device

This device is similar in design and construction, and has the same indications for use and performance characteristics to the predicate device. Epicardia Anywhere will be cloud hosted and accessible from across the Internet using popular web browsers. It will retain all the major functionality of Epicardia 5000. No new issues of safety or effectiveness are introduced by using this device.

D. Argument for Substantial Equivalence to Predicate Device

The indications for use and the technological characteristics of Epicardia Anywhere remain the same as predicate device and therefore we believe it is Substantially Equivalent to the predicate device.

7. NON-CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTAIL EQUIVALENCE

Testing information demonstrating safety and effectiveness of Epicardia Anywhere in the intended environment of use is supported by testing that was conducted in accordance with National and International Standards.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate devices:

The following National and International Standards were utilized for testing the subject device:

1) ANSI/AAMI EC57:1998/(R)2008 Testing and Reporting Performance Results of Cardiac Rhythm and St-Segment Measurement Algorithms

2) AAMI / ANSI / ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices - Application of risk management to medical devices

3) AAMI / ANSI / IEC 62366:2007/(R)2013 Medical Devices - Application of Usability Engineering to Medical Devices

Relevant Guidances:

1. Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm (2003)
2. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005)
3. Premarket Assessment of Pediatric Medical Devices (2015)

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Epicardia Anywhere testing met all relevant requirements of the aforementioned tests and therefore, the subject device does not introduce any new issue of safety or effectiveness and is substantially equivalent to the predicate device.

8. CLINICAL TESTING

Not Applicable

9. SOFTWARE

Epicardia Anywhere is similar in design and construction, and has the same indications for use and performance characteristics to the predicate device. It utilizes functionality that are already in use in other medical devices. No new issues of safety or effectiveness are introduced by using this device.

10. CONCLUSION

The subject device, Epicardia Anywhere, has identical indications for use as the predicate device, Epicardia 5000. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. Therefore, Epicardia Anywhere is substantially equivalent to the predicate device, Epicardia 5000, K090834.