DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 24, 2017

GETEMED Medizin- und Informationstechnik AG
Bert Schadow
Regulatory Affairs Manager
Oderstrasse 77
Teltow, 14513 DE

Re: K162023
Trade/Device Name: CardioDay V2.5
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: July 19, 2016
Received: July 22, 2016

Dear Bert Schadow:

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.

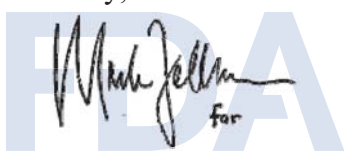
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,



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)*

K162023

Device Name
CardioDay V2.5

Indications for Use *(Describe)*

The CardioDay V2.5 Holter Analysis Software is designed for the acquisition, analysis, edit, review, report, and storage of ambulatory and multi-parameter ECG data.
Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data.
The CardioDay V2.5 system is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment.
Patient population includes both adult and pediatric human patients.
CardioDay V2.5 provides the user arrhythmia study and Holter analysis capabilities.
Data acquired may be used for the following indications:

- Evaluation of symptoms that may be caused by cardiac arrhythmia and/or conduction disturbances,
- Evaluation of symptoms that may be due to myocardial ischemia,
- Detection of ECG events that alter prognosis in certain forms of heart disease,
- Detection and analysis of pacemaker function and failure,
- Determination of cardiac response to lifestyle,
- Evaluation of therapeutic interventions,
- Investigations in epidemiology and clinical trials.

Prescription Device Statement:
United States federal law restricts CardioDay to sale by or on the order of a physician.

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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1 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is: K162023.

Submitted By:
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Manufacturing Facility:
GETEMED Medizin- und Informationstechnik AG
Oderstrasse 77, 14513 Teltow, GERMANY

Date of Preparation: March 22, 2017

Name of the Device: CardioDay® V2.5

Common or Usual Name: Holter evaluation software

Classification Name: Computer, Diagnostic, Programmable

Product Classification: 21 CFR 870.1425, Class II

Product Code: DQK

Predicate Device Information:

Device	Manufacturer	510(k) Number
Primary Predicate Device: CardioDay® version 2.4	GETEMED Medizin- und Informationstechnik AG	K130516
Secondary Predicate Device: MARS Holter Analysis Workstation	GE Medical Systems Information Technologies	K132437

2 Reason for Submission

Premarket notification for CardioDay® V2.5, a New Device, seeking authority to market the device under Section 510(k) as a device that is substantially equivalent to the evaluation software CardioDay version 2.4 (K130516, GETEMED Medizin- und Informationstechnik AG) and MARS (K132437, GE Medical Systems Information Technologies).

3 Device Description

CardioDay® is a software package that allows a trained physician or health care professional knowledgeable in Holter interpretation, after having performed a long-term continuous electrocardiographic (ECG) recording, to download and analyze the data, review it and produce printed reports. CardioDay® does not perform any diagnosis of data by itself but only displays ECG morphologies and associated, calculated graphs such as heart rate trends, RR variability, and other statistical values in graphical form. The physician will be able to review, edit, and print the data collected.

The following Interfacing Devices (not part of this 510(k)) are supported by CardioDay V2.5:

- CardioMem CM 3000 (identical to CardioDay V2.4)
- CardioMem CM 3000Z (identical to CardioDay V2.4)
- CardioMem CM 3000-12BT (identical to CardioDay V2.4)
- CardioMem CM 4000(B) (identical to CardioDay V2.4)
- SEER 12 (identical to CardioDay V2.4)
- SEER Light (new in CardioDay V2.5)
- SEER Light Extend (new in CardioDay V2.5)
- SEER 1000 (24h, 48h and 7-day models) (identical to CardioDay V2.4)
- Care Scape Gateway (new in CardioDay V2.5)

4 Intended Use

The CardioDay V2.5 Holter Analysis Software is designed for the acquisition, analysis, edit, review, report, and storage of ambulatory and multi-parameter ECG data.
Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data.
The CardioDay V2.5 system is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment.
Patient population includes both adult and pediatric human patients.
CardioDay V2.5 provides the user arrhythmia study and Holter analysis capabilities.
Data acquired may be used for the following indications:

- Evaluation of symptoms that may be caused by cardiac arrhythmia and/or conduction disturbances,
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- Detection and analysis of pacemaker function and failure,
- Determination of cardiac response to lifestyle,
- Evaluation of therapeutic interventions,
- Investigations in epidemiology and clinical trials.

Prescription Device Statement:
United States federal law restricts CardioDay® to sale by or on the order of a physician.

5 Comparison to Predicate Devices

The primary predicate device is CardioDay version 2.4 (K130516). There have been no changes implemented in the modifications to CardioDay® V2.5 that impact the fundamental technology. The indications for use from CardioDay® version 2.4 (K130516) was adapted to the indications for use from MARS (K132437) in order to clarify the indications without affecting the substance or meaning of the indications.
As all indications for use cover the same diagnostic scope, i.e. patients suffering from cardiac related illnesses or complaining of potentially having such illnesses, as well as patients wearing a pacemaker, the Holter evalution software CardioDay® V2.5 can be regarded as substantially equivalent to CardioDay® version 2.4 (K130516) from GETEMED Medizin- und Informationstechnik AG and MARS Holter Analysis Workstation (K132437) from GE Medical Systems Information Technologies.

The following incremental changes were also made:
- Graphical user interface → OEM Version for GE Healthcare;
- MUSE Import/Export Option (order management implemented);
- ECG Monitor Import Option (via Carescape Gateway from GE Healthcare) and support of SEER Light Holter recorders;
- Software Licensing Concept with Single Sign-On;
- Bluetooth Hook-Up Process for SEER 1000 Holter recorders;
- Error Logging implemented

A detailed discussion of similarities and differences is provided as a table of comparison in this 510(k) submission.

6 Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows

Non-clinical testing that has been conducted includes:
a. ECG performance testing according to AAMI / ANSI / IEC 60601-2-47;
b. Software development life cycle according to IEC 62304;
c. Risk management process according to AAMI / ANSI / ISO 14971 and IEC /TR80002-1;
d. Usability engineering process according to AAMI / ANSI / IEC 62366-1 and IEC 60601-1-6;
e. Security tests to fulfill FDA Guidance for cybersecurity;
f. Interface tests to fulfill FDA Guidance for interoperability.

None of the testing demonstrated that CardioDay® V2.5 brought up any issues of safety or effectiveness.

7 Discussion of Clinical Tests Performed

No clinical testing was performed in order to support safety or effectiveness.

8 Conclusion

CardioDay® V2.5 is identical to its predicate device in intended use / indications for use and operating principle. Verification and validation of CardioDay V2.5 demonstrated that the incremental changes do not raise any new questions of safety and effectiveness to the subject device and the subject device is substantially equivalent to the predicate devices.