July 30, 2018

Epiphany Healthcare, LLC
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K181720
Trade/Device Name: Epiphany Cardio Server Mobile
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK
Dated: June 28, 2018
Received: June 29, 2018

Dear Mark Job:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181720

Device Name
Epiphany Cardio Server Mobile

Indications for Use *(Describe)*

Epiphany Cardio Server Mobile is a software application used for accessing and displaying ECG data and related patient information previously stored, analyzed or received by the Cardio Server ECG Management System. The Epiphany Cardio Server Mobile software application is intended to be used from a mobile device to perform the following:

• View ECG test results, such as waveforms, measurements and diagnosis statements as well as other relevant current or historical patient information originally stored, analyzed or received by the Cardio Server ECG Management System.

• View the ECG lead traces using different display settings.

• Compare the results of current ECG tests with the patient's previous ECG test results stored on the Cardio Server ECG Management System.

• Perform manual ECG-related measurements using the electronic caliper tool.

• Communicate information with the Cardio Server ECG Management System such as login credentials and user settings.

Epiphany Cardio Server Mobile application is intended to be used under the direct supervision of a licensed healthcare practitioner and by trained operators. Epiphany Cardio Server Mobile is not intended for real time monitoring.

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.

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510(k) SUMMARY
Epiphany Cardio Server Mobile

Epiphany Healthcare, LLC
3000 E. Boundary Terrace, Suite 2
Midlothian, VA 23112

Contact Person: Pat White
Phone: 336-617-7923
Fax: 703-991-2501

Date Prepared: July 27,2018

Name of the device:	Epiphany Cardio Server Mobile
Common Name:	Cardio Server Mobile
Classification Name:	Programmable Diagnostic Computer/ 870.1425
Classification Regulation:	21 CFR 870.1425
Product code:	DQK
Device Class:	Class II
Primary Predicate Device:	McKesson Cardiology ECG Mobile (K133534)
Reference Predicate Device:	Cardio Server ECG Management System (K052883)

Intended Use / Indications for Use
Epiphany Cardio Server Mobile is a software application used for accessing and displaying ECG data and related patient information previously stored, analyzed or received by the Cardio Server ECG Management System. The Epiphany Cardio Server Mobile software application is intended to be used from a mobile device to perform the following:

- View ECG test results, such as waveforms, measurements and diagnosis statements as well as other relevant current or historical patient information originally stored, analyzed or received by the Cardio Server ECG Management System.
- View the ECG lead traces using different display settings.
- Compare the results of current ECG tests with the patient's previous ECG test results stored on the Cardio Server ECG Management System.
- Perform manual ECG-related measurements using the electronic caliper tool.

- Communicate information with the Cardio Server ECG Management System such as login credentials and user settings.

The Epiphany Cardio Server Mobile application is intended to be used under the direct supervision of a licensed healthcare practitioner and by trained operators. The Epiphany Cardio Server Mobile application is not intended for real-time monitoring.

Technological Characteristics

The Epiphany Cardio Server Mobile provides secure access to ECG records and related information contained on the Cardio Server ECG Management System. The Epiphany Cardio Server Mobile software functions as an accessory to the Cardio Server ECG Management System, and requires a WIFI or cellular connection to a pre-installed and properly configured Cardio Server ECG Management System. Through providing remote access to the ECG data stored on the Cardio Server ECG Management System, the user is able to review current and previous ECG tests, results, and perform measurements on the ECG waveforms. Cardio Server Mobile does not store ECG or patient related information on the mobile device, does not directly communicate with cardiographs or other waveform acquisition devices, and does not use any automatic electronic data processing and pattern recognition methods to derive measurements (e.g. intervals and amplitudes) or provide diagnostic statements from the ECG data. The device does not allow modification of the original ECG traces (waveforms) stored on the Cardio Server ECG Management System.

The Epiphany Cardio Server Mobile application is not intended to replace the functionalities provided by the Cardio Server ECG Management System desktop client but to extend those to make selected functionalities described above available via mobile devices.

The Epiphany Cardio Server Mobile functions as a non-real time system and is not intended for real time monitoring.

The Epiphany Cardio Server Mobile can be used both inside and outside of medical facilities except in areas where cellular phone or wireless device use is prohibited.

The Epiphany Cardio Server Mobile is intended to operate on Apple iPad and iPhone running iOS mobile operating system from Apple Inc.

Comparison of Technological Characteristics with the Predicate Device

(See table below.)

Comparison of Technological Characteristics with the Predicate Device

Number	Description	Epiphany Cardio Server Mobile	McKesson Cardiology ECG Mobile (K133534)
1	Intended Use/Indications for Use		
1.1	View ECG test results from a mobile device, including waveforms, measurements, and diagnosis statements.	Yes	Yes
1.2	View current or historical patient information originally stored, analyzed, or received by the device to which this device is an accessory.	Yes	Yes
1.3	View ECG lead traces using optional display settings.	Yes	Yes
1.4	Compare the results of current ECG tests with any previous ECG test results stored on the device to which this device is an accessory.	Yes	Yes
1.5	Perform ECG related measurements using electronic calipers.	Yes	Yes
1.6	Communicate information with the device to which this device is an accessory, such as login credentials and user settings.	Yes	Yes
1.7	Does not store patient information or test results on the mobile device.	Yes	Yes
1.8	Does not provide real-time monitoring.	Yes	Yes
2	Target Population		
2.1	To be used under direct supervision of a licensed healthcare practitioner and by trained operators.	Yes	Yes
3	Performance		
3.1	Non-clinical testing included software verification, validation, and security testing.	Yes	Yes
4	Materials		
4.1	Software only.	Yes	Yes
5	Compatibility with the environment and other devices		
5.1	Requires WIFI or cellular connection to access data.	Yes	Yes
5.2	Compatible with Apple iPhone and iPad.	Yes	Yes
5.3	Compatible with iOS 10 and later.	Yes	Yes
5.4	Compatible with iOS 7.x, 8.x, 9.x versions.	No	Yes
6	Where Used		
6.1	To be used in hospital or any remote location that allows mobile device use, cell phone use, or WIFI use.	Yes	Yes
6.2	To be used under the direct supervision of a licensed healthcare practioner and by trained operators.	Yes	Yes
7	Not applicable to the above devices		
7.1	Thermal Safety	No	No
7.2	Mechanical Safety	No	No
7.3	Sterility	No	No
7.4	Biocompatibility	No	No
7.5	Electrical Safety	No	No
7.6	Chemical Safety	No	No
7.7	Radiation Safety	No	No
7.8	Anatomical Site	No	No
7.9	Energy Used and/or Delivered	No	No

Performance Data

Non-clinical testing performed included software verification, validation, and security testing to ensure that the Cardio Server Mobile met all design specifications and requirements. Unit and system level testing included assurance of operability with the predicate McKesson Cardiology ECG Mobile application and user accuracy qualification of ECG waveform and related information representation in a simulated user test environment.

Bench testing performed verified the Cardio Server Mobile display and measurements capabilities using sample cases based on technical characteristics and relevancy to the intended function of the Epiphany Cardio Server Mobile application. The testing considered different display manipulations (e.g., full-screen display, zoom, navigating between screens, device orientation), display quality, and display accuracy when compared to the original data as presented by Cardio Server ECG Management System. In particular, the testing was performed to ensure adequate user readability and image quality on a small screen.

In all instances, the Epiphany Cardio Server Mobile functioned as intended by the design requirements and the observed results demonstrated substantial equivalence with the predicate device.

Substantial Equivalence

The Epiphany Cardio Server Mobile has the same intended use, similar indications, technological characteristics and principles of operation as the predicate device. Both devices display ECG tracings and procedure data, and allow for manual waveform measurements.

Any differences between the predicate device and Epiphany Cardio Server Mobile do not raise any new questions related to safety and effectiveness. Based on the performance test results, the Epiphany Cardio Server Mobile is substantially equivalent to the McKesson Cardiology ECG Mobile (K133534).