Bay Labs, Inc.
% Yarmela Pavlovic
Partner
Hogan Lovells US LLP
3 Embarcadero Center, Suite 1500
SAN FRANCISCO CA 94111

June 14, 2018

Re: K173780
Trade/Device Name: EchoMD Automated Ejection Fraction Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 22, 2018
Received: May 22, 2018

Dear Yarmela Pavlovic:

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 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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K173780

Device Name

Bay Labs, Inc. EchoMD Automated Ejection Fraction Software

Indications for Use *(Describe)*

The Bay Labs, Inc. EchoMD Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using a personal computer or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.

The EchoMD Automated Ejection Fraction Software is indicated for use in adult patients.

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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510(k) SUMMARY

Bay Labs, Inc.
EchoMD Automated Ejection Fraction Software

Submitter's Name, Address, Telephone Number, Contact Person

Bay Labs, Inc.
290 King Street, Suite 9
San Francisco, CA 94107

Contact Person: Charles Cadieu, CEO
Phone: 415 671 4711
email: charles@baylabs.io

Date Prepared: May 21, 2018

Name of Device

Common or Usual Name: Picture Archival and Communications Systems Workstation

Proprietary Name: EchoMD Automated Ejection Fraction Software

Classification Name: 21 CFR § 892.2050

Regulatory Class: II

Product Code: LLZ, System, Image processing, Radiological

Predicate Device

Diacardio, Ltd. LVivo EF Software (K130779)

Intended Use / Indications for Use

The Bay Labs, Inc. EchoMD Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using a personal computer or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.

The EchoMD Automated Ejection Fraction Software Application is indicated for use in adult patients.

The intended use/indications for use statement is worded slightly differently than that of the predicate device, but the minor differences do not alter the intended diagnostic effect of the subject device; both products are intended to process echocardiogram images and produce ejection fraction calculations. The minor differences also do not raise different questions of safety or effectiveness, as in both instances the key question is whether the software can both produce ejection fraction calculations acceptable for clinical use.

Device Description

The EchoMD Automated Ejection Fraction (AutoEF) software applies machine learning algorithms to process echocardiography images in order to calculate left ventricular ejection fraction. The software operates in between the DICOM source and the DICOM destination. EchoMD AutoEF performs left ventricular ejection fraction measurements using both the apical four chamber and apical two chamber cardiac ultrasound views.

The software selects the image clips to be used, performs the AutoEF calculation, and forwards the results to a destination PACS server for clinician viewing. The output of the program is the Ejection Fraction estimate stated as a percentage, which is displayed via the destination PACS system. The software applies machine learning algorithms to assess image quality and provides this information as qualitative and quantitative user feedback. By automating the estimation of ejection fraction, the EchoMD software is designed to streamline the clinician's calculation of the measurement.

Summary of Technological Characteristics

The technological principle underlying both the EchoMD AutoEF and the predicate device is the calculation of ejection fraction (EF) on previously acquired cardiac scans using machine learning-based algorithms and biplane apical echocardiographic images. Ultimately, the key question for both products is whether the EF calculation provides adequate information for the clinician.

While the two products use slightly different approaches to achieving their shared purpose, these differences do not raise different questions of safety or effectiveness. EchoMD AutoEF operates as a microservice background function communicating with ultrasound systems and PACS workstation systems, which provide the user interface. The predicate device may operate in this manner but also is configurable to provide its own user interface. EchoMD AutoEF automates the selection of image video clips on which to operate. The predicate device includes manual user selection of image video clips. EchoMD AutoEF utilizes a convolutional neural network design which operates on the image data in order to estimate ejection fraction without creating endocardial traces. The predicate generates endocardial traces. Other minor differences arise due to the design of the EchoMD running as part of a PACS system, rather than as a fully stand-alone application like the predicate.

A tabular comparison of the key features of the subject and predicate devices is provided at the end of this Summary.

Performance Data

EchoMD EF software was developed and tested in accordance with Bay Labs' Design Control processes and has been subjected to extensive safety and performance testing. Non-clinical verification and validation test results established that the device meets its design requirements and intended use. Specifically, software verification was conducted at unit, module, and system integration levels. Risk management analysis generated multiple risk mitigation measures and verification activities. A Cybersecurity Analysis and data security testing were conducted to verify that data and patient protected health information security measures are included in the design of the software.

Verification and validation testing was conducted to demonstrate the substantial equivalence of EchoMD AutoEF. In both tests, the success criterion was that the EchoMD AutoEF would produce an

ejection fraction number with a Root Mean Square Deviation below a set threshold as compared to the reference ground truth EF.

A formal retrospective, non-interventional validation study was conducted using over 300 previously-acquired studies where the biplane method of disks ejection fraction was reported. This patient dataset was constructed to provide a balanced range of gender, ejection fraction values, and body mass index levels. Testing included a wide array of ultrasound system manufacturers to verify that EchoMD AutoEF performs acceptably across multiple scanner platforms. Variability testing was also performed to demonstrate that EchoMD AutoEF performs acceptably with a variety of image clips and frames from the same patient. Test datasets were strictly segregated from algorithm training datasets. EchoMD AutoEF ejection fraction measurements were compared to the biplane method ejection fraction, and a root mean square deviation was calculated and used as the primary endpoint. The primary endpoint was met (results: 8.290% RMSD, p-value 0.00052). An additional study was performed with a different set of cardiologists on a subset of the validation patient studies to further demonstrate the generalizability of the software. Based on the clinical performance as documented in this pivotal clinical study, the device has a safety and effectiveness profile that is similar to the predicate Diacardio LVivo EF Software device.

Conclusion

The EchoMD AutoEF Software is as safe and effective as the Diacardio LVivo EF Software. The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the EchoMD AutoEF and its predicate device do not raise different questions of safety or effectiveness. Performance data demonstrate that the subject device is as safe and effective as the identified predicate. Thus, the EchoMD Automated Ejection Fraction Software is substantially equivalent.

Comparison Table: EchoMD AutoEF versus Predicate

	Bay Labs EchoMD Automated Ejection Fraction Software Application	**DiaCardio, Ltd, LVivo EF Software Application** (K130779, Predicate)
Product Code	LLZ	LLZ
Intended Use	The Bay Labs, Inc. EchoMD Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using a personal computer or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.	DiaCardio's L Vivo EF Software Application is intended for non-invasive processing of already acquired echocardiographic images in order to detect, measure, and calculate the left ventricular wall for left ventricular function evaluation. This measurement can be used to assist the clinician in a cardiac evaluation.
Machine Learning-Based Algorithm	Yes	Yes

	Bay Labs EchoMD Automated Ejection Fraction Software Application	**DiaCardio, Ltd, LVivo EF Software Application** (K130779, Predicate)
Operates on DICOM clips	Yes	Yes
Automation level	Fully automated, including clip selection	Fully automated (with manually-selected clips)
EF Method	Biplane (non-segmentation/non-endocardial trace)	Biplane Method of Disks Segmentation (endocardial trace)
Offline EF evaluation using clips from multiple ultrasound scanners	Yes	Yes
Image Clip Selection	Automated	Manual
Automated Ejection Fraction Calculation	Yes	Yes
Ejection Fraction reported	Whole number estimate (percentage)	Whole number estimate (percentage)
Algorithm Confidence	Qualitative and quantitative user feedback on transthoracic cardiac ultrasound image quality	Display of endocardial border tracing
EF Result shown with video clip	Yes	Yes
User confirmation/ rejection of result	Yes	Yes
Manual editing of automated result by user	Yes (on PACS workstation)	Yes (in application)
Left ventricular volumes measurements	Not internal. Uses manual trace option PACS workstation	Yes