Dyad Medical, Inc
℅ Yervant Chijian
Regulatory and Quality Consultant
Pharmalex Pty Ltd
Suite 10.4, 1 Chandos Street
St. Leonards, NSW 2068
AUSTRALIA

July 20, 2022

Re: K220956
　　Trade/Device Name: Libby Echo:Prio
　　Regulation Number: 21 CFR 892.2050
　　Regulation Name: Medical image management and processing system
　　Regulatory Class: Class II
　　Product Code: QIH
　　Dated: June 17, 2022
　　Received: June 21, 2022

Dear Yervant Chijian:

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 and Part 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices
 and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number *(if known)*
K220956

Device Name
Libby™ Echo:Prio

Indications for Use *(Describe)*
Libby™ Echo:Prio is software that is used to process previously acquired DICOM-compliant cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements.

The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making.

Libby™ Echo:Prio 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.

**5 510(k) Summary – Libby™ Echo:Prio**

## 5.1 General Information

| 510(k) Sponsor | Dyad Medical, Inc |
|---|---|
| Address | 215 Brighton Avenue, Suite 203<br>Boston, MA 02134 |
| Correspondence Person | Yervant Chijian<br>Quality and Regulatory Consultant<br>Pharmalex Pty Ltd |
| Contact Information | Email: Yervant.Chijian@pharmalex.com<br>Phone: +61 (0)2 9906 2984 |
| Date Prepared | 31st March 2022 |

## 5.2 Subject Device

| Proprietary Name | Libby™ Echo:Prio |
|---|---|
| Common Name | Echo:Prio |
| Classification Name | System, Image Processing, Radiological |
| Regulation Number | 21 CFR 892.2050 |
| Regulation Name | Automated Radiological Image Processing Software |
| Product Code | QIH |
| Regulatory Class | II |

## 5.3 Predicate Device

| Proprietary Name | EchoMD Automated Ejection Fraction Software |
|---|---|
| Premarket Notification | K173780 |
| Classification Name | System, Image Processing, Radiological |
| Regulation Number | 21 CFR 892.2050 |
| Regulation Name | Picture archiving and communications system |
| Product Code | LLZ |
| Regulatory Class | II |

## 5.4 Device Description

Echo:Prio is an image post-processing analysis software device used for viewing and quantifying cardiovascular ultrasound images. The device is intended to aid diagnostic review and analysis of echocardiographic data, patient record management and reporting.

The software provides an interface for a skilled sonographer to perform the necessary markup on the echocardiographic image prior to review by the prescribing physician. The markup includes: the cardiac segments captured, measurements of distance, time, area, quantitative analysis of cardiac function, and a summary report.

The software allows the sonographer to enter their markup manually and/or manually correct automatically generated results. It also provides automated markup and analysis, which the sonographer may choose to accept outright, to accept partially and modify, or to reject and ignore. Machine learning based view classification and border segmentation form the basis for this automated analysis. Additionally, the software has features for organizing, displaying, and comparing to reference guidelines the quantitative data from cardiovascular images acquired from ultrasound scanners.

The following visualization, quantification and data-reporting functionalities are provided by the software:

### 5.4.1 Visualization:

- 2D image review
- Cine loop review
- Secondary captures review

### 5.4.2 Quantification of classification, segmentation and index calculations:

- Echocardiographic View classification
- End diastole (ED) and End systole (ES) frame identification enabling Heartbeat rate (HR) estimates.
- Ejection fraction (EF)

*Notes:* This is achieved via automatic left ventricle (LV) chamber endocardium segmentation, left atrium (LA) segmentation, LV myocardium (LVMC) segmentation allowing muscle thickness calculations.

### 5.4.3 Data reporting

All the above values are reported via a report generation initiated by the investigator.

## 5.5 Indications for Use

Libby Echo:Prio is software that is used to process previously acquired DICOM-compliant cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making.
Libby Echo:Prio is indicated for use in adult patients.

## 5.6 Substantial Equivalence

The following table demonstrates the similarities and differences between the technological characteristics of the three products. Testing demonstrates that the differences do not raise new questions of safety or effectiveness.

**Table 1:** Libby™ Echo:Prio Device Comparison.

| Topic | Subject Device<br>*Libby™ Echo:Prio* | Predicate Device<br>*EchoMD Automated Ejection Fraction Software* | Substantial Equivalence |
|---|---|---|---|
| **Intended Use/Indications for Use** | Libby™ Echo:Prio is software that is used to process previously acquired DICOM-compliant | The Bay Labs, Inc. EchoMD Automated Ejection Fraction software is used to process | Same |

| Topic | Subject Device<br>*Libby™ Echo:Prio* | Predicate Device<br>*EchoMD Automated Ejection Fraction Software* | Substantial Equivalence |
|---|---|---|---|
| | cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making.<br>Libby™ Echo:Prio is indicated for use in adult patients. | 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 EjectionFraction Software is indicatedfor use in adult patients. | |
| Intended User | Cardiologists and sonographers | Cardiologists and sonographers | Same |
| Rx or OTC | Rx | Rx | Same |
| Intended Location | Medical facility | Medical facility | Same |
| High Level Device Description | The Libby™ Echo:Prio is an image post-processing analysis software device used for viewing and quantifying cardiovascular ultrasound images. | EchoMD software is process acquired transthoracic cardiac ultrasound images, to analyze and make measurements on images in order to provide automated estimation of left ventricular ejection fraction | Same |
| Automated Chamber analysis Features & Analysis | Yes | Yes | Same |
| Automated measurements | LV Ejection fraction (EF) | Left ventricular ejection fraction | Same |
| Machine Learning Based Algorithm | Yes | Yes | Same |
| Operate on DICOM clips | Yes | Yes | Same |
| Automated View Classification including:<br>1. long axis view (PLAX)<br>2. short axis view (PSAX)<br>3. four-chamber view (A4C)<br>4. five-chamber view (A5C)<br>5. two-chamber view (A2C)<br>6. long axis view (A3C) | Yes | Yes | Same |
| Automation Level | Fully automated, including clip selection | Fully automated, including clip selection | Same |
| Algorithm Confidence | Qualitative user feedback on transthoracic cardiac ultrasound image quality | Qualitative and quantitative user feedback on transthoracic cardiac ultrasound image quality | Same |
| EF Method | Single plane & biplane (with segmentation and endocardial trace) | Biplane (non-segmentation/ non-endocardial trace) | Same |

| Topic | Subject Device<br>*Libby™ Echo:Prio* | Predicate Device<br>*EchoMD Automated Ejection Fraction Software* | Substantial Equivalence |
|---|---|---|---|
| **Offline EF evaluation using clips from multiple ultrasound scanners** | Yes | Yes | Same |
| **Automated Ejection Fraction Calculation** | Yes | Yes | Same |
| **Ejection Fraction reported** | Whole number estimate (percentage) | Whole number estimate (percentage) | Same |
| **User Confirmation/rejection of result** | Yes | Yes | Same |
| **Manual editing of automated result by user** | Yes | Yes | Same |
| **Physical Characteristics** | Software package that operates on off-the-shelf hardware | Software package that operates on off-the-shelf hardware | Not equivalent but no issues with safety and efficacy. |
| **DICOM Standard Compliance** | The software processes DICOM compliant image data | The software processes DICOM compliant image data | Same |
| **Modalities** | Ultrasound | Ultrasound | Same |
| **User Interface** | The software is designed for use within a web browser on a personal computer. | The software is designed for use on personal computer or a compatible DICOM-compliant PACS system. | Not equivalent but no issues with safety and efficacy. |

## 5.7    Performance Data

Safety and performance of the Libby™ Echo:Prio has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/AC: 2008- Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

Performance Testing demonstrated robustness and accuracy retrospectively on a diverse clinical dataset. This demonstrates consistent analysis and low inter/intra-analyst variability of the automated procedures.

The testing demonstrated view classification accuracy of 97% with an average F1 value of >96.6%, average sensitivity (Sn) of 96.8% and average Specificity (Sp) of 98.5%. The testing also demonstrated that the HR output estimate is with minimal bias (slope of 0.98 in linear regression with confidence interval of 95%) compared to the ground truth (12-lead ECG) also showing exceptional accuracy in ED/ES identification.

Finally, the prediction of the EF output using the Libby™ Echo:Prio software had a slope of 0.79 for Bivariate Linear Regression (BLS) with the 95% confidence interval (CI) of (0.52, 0.98) compared with the annotations by four human experts. This is well within the range of typical measurement variation between different clinicians, which is usually described as inter-observer variation and can be as low as (0.37, 0.52) of the 95% CI.

## 5.8 Standards Applied

The standards applied for the development of the software is listed below:

- NEMA PS 3.1 - 3.20 2021e Digital Imaging and Communications in Medicine (DICOM) Set
- IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes
- ISO 14971:2019 Medical Devices -- Application of Risk Management to Medical Devices
- IEC 62366-1 Edition 1.1 2020-06 Medical Devices -- Part 1: Application of Usability Engineering to Medical Devices
- 21 CFR 820 Quality System Regulations
- ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

## 5.9 Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the Libby™ Echo:Prio raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.