DiA Imaging Analysis Ltd.
% George Hattub
Medical Device Regulatory Affairs Specialist
Medicsense USA LLC
291 Hillside Avenue
Somerset, Massachusetts 02726

March 17, 2025

Re: K243862
Trade/Device Name: LVivo Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 21, 2025
Received: February 21, 2025

Dear George Hattub:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

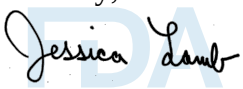
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, PhD
Assistant Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243862

Device Name

LVivo Software Application

Indications for Use *(Describe)*

LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease and Age >18. In addition, it has the ability to provide Quality Score feedback.

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 K243862

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a) Submitter Address:

George J. Hattub
Medicsense USA LLC
291 Hillside Avenue
Somerset, MA 02726
ghattub@comcast.net

1. (b) ***Manufacturer Address:*** DiA Imaging Analysis Ltd
HaEnergia Street 77
Beer-Sheva, Israel 8470912

Mfg. Phone: Tel.: +972 77 7648318

Contact Person: Mrs. Michal Yaacobi

Date: Mach 16, 2025

2. ***Device & Classification Name:*** Medical Image Management and Processing System – classified as Class 2 QIH, Regulation Number 21 CFR 892.2050
LVivo Software Application

3. ***Predicate Devices:*** LVivo Software Application K240553

4. ***Description:***

The LVivo platform is a software system for automated analysis of ultrasound examinations. Automated analysis of echocardiographic examinations is done using DICOM movies. The LVivo platform supports global and segmental evaluation of the left ventricle (LV) of the heart utilizing the apical views. Global LV function evaluation by ejection fraction (EF) is done based on two of the apical views: four-chamber (4CH) and two-chamber (2CH). Segmental LV function evaluation is done from three apical views 4CH, 2CH and three chamber (3CH) and supports segmental wall motion evaluation and strain. The LVivo platform supports also LV function evaluation from the parasternal views including global and segmental LV function analysis from the Short Axis (SAX) view and the global LV function analysis form the Parasternal Long Axis (PLAX) views.

In addition to the LV analysis, the cardiology toolbox includes a module for automated evaluation of the Right Ventricular function. The LVivo platform includes one additional non-cardiac module for the measurement of the bladder volume.

The LVivo Platform includes also two additional configurations: LVivo Seamless for offline analysis based on automatically selected views and LVivo IQS for real-time quality feedback during image acquisition

5. ***Indications for Use:*** LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of

structures and function of patients with suspected disease and Age>18. In addition, it has the ability to provide Quality Score feedback.

6. ***Comparison of Technological Characteristics:***

With respect to technology and intended use, DiA's LVivo *Software Application* is substantially equivalent to its predicate devices. Based upon the outcomes from the risk analysis and Performance Testing Evaluation, DiA believes that the modification of LVivo SWM module of the LVivo Software Application predicate device does not raise additional safety of efficacy concerns. The following comparison table depicts the changes.

	Submitted Device	**Predicate Device**
Features/Characteristics	**LVivo Software Application**	**LVivo Software Application**
Product Code	same	QIH
Indication for Use	LVivo platform is intended for non- invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease and Age >18. In addition, it has the ability to provide Quality Score feedback	LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease. In addition, it has the ability to provide Quality Score feedback
Modules	same	LVivo PLAX, LVivo IQS, LVivo EF, LVivo SG, LVivo SAX, LVivo RV, LVivo Seamless & LVivo Bladder
Automation	same	yes
Manual Adjustment	same	yes
Bi plane EF evaluation	same	yes
Simultaneous 2CH and 4CH evaluation	same	yes
Off-line LV RV and Bladder evaluation using DICOM clips of any vendor	same	yes

Automated ED and ES frames selection	same	yes
Manual ED and ES frames selection	same	yes
Dynamic left ventricular Manual editing by user capability	same	yes
Manual editing by user capability	same	yes
Visually confirm results	same	yes
Automated rejection of false results	same	yes
Volume calculation by standard Simpson's method of discs for	same	yes
Volume curve Presentation	same	yes
EF, Strain, SWM, RV, SAX, Bladder results presentation	same	yes
Enables presentation of cardiac function results for different	same	yes
Algorithm	same	yes
Calculation speed	same	yes
Capability or a part of a bigger package (device) for LV function evaluation and Bladder	same	yes
Segmental Longitudinal Strain Measure	same	yes
Global Longitudinal Strain Measure	same	yes

Segmental wall motion evaluation	Yes. Based on the same machine learning algorithm, multiple rocessing steps were added and the calculated features revised	Yes. Based on a machine learning algorithm.
Operating System	Same	Windows/Linux(With Android option for LVivo EF
510(k) #	Pending	K240553

Non-Clinical Performance Evaluation:

The proposed modification of LVivo software application was tested in accordance with DiA Imaging Analysis internal procedures. DiA imaging Analysis tested the subject devices per the following standards to ensure the continued safe and effective performance:

- IEC 62304:2006+A1:2015 CSV, Medical Device Software – Software Life-Cycle Processes
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices, 2015 + AMD 2020.
- IEC/TR80002-1:2009, Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software systems, software, and services information

Non-clinical verification testing was conducted to address the change and performance test data were provided to support the revision of the software application. The activities to assure the safe and effective performance of the software revision included, but are not limited to, the Requirements Review, Risk Analysis and System Testing.

Risk control measures are identified by the threat models and incorporated into the risk analysis process and SW design. The verification and validation testing including 3rd party libraries vulnerability assessment of the SW (SBOM) to ensure that cybersecurity related design requirement are implemented successfully. The company has defined a Cybersecurity plan for ongoing cybersecurity maintenance.

7. ***Clinical Performance Evaluation:***

A summary of the Performance Evaluation, which was based upon well-established test methods, demonstrated conformity to the intended use.

The validation was done using 170 examinations echo exams acquired with GE and Philips ultrasound devices. The exams were collected in three medical centers, 101 exams from a medical center in US, 69 exams from two medical centers in Israel. The patient population included 66% male with mean age of 60.5 ±14.9 years. BMI information was available for the examination in US and was reported to be 30.9 ± 8.

Global systolic LV function was normal in 48 (28%) of the patients. Regional wall motion abnormalities (RWMA) were indicated in over 73 (42.9%) patients. Inclusion criteria: Age ≥18, sinus rhythm without multiple premature beats. Examinations in which more than one third of the endocardium is not visible in a plane (2CH/4CH/3CH) and patients with LBBB were excluded from the study.

Ground truth was defined as WMSI average across three cardiologists specializing in echo.

Results

A total of 166 exams were processed, automated analysis was possible in 139 exams (84%). The Specificity and sensitivity of WMSI were 79% and 82% respectively and the accuracy was found to be 82%. The Pearson correlation coefficient between automatically calculated WMSI was 0.89

The ICC calculation to compare between the automated WMSI and ground truth, was based on the exams that were processed automatically by the algorithm. In the ICC calculation to compare between the three experts, all patients in which WMSI was provided in the ground truth from all three experts were included. The comparison for

ICC				
	GT vs LVivo SWM	Expert 1 vs Expert 2	Expert 1 vs Expert 3	Expert 2 vs Expert 3
WMSI	0.85	0.64	0.74	0.81

WMSI is provided below:

ICC calculated between GT and LVivo SWM, and between each pair of experts.

The software was tested on additional data set of 101 patients collected from a hospital in Taiwan. The data was acquired with Philips ultrasound device.

The patient population consisted of 62% males, with a mean age of 70.1 ± 16 years (range: 29–99 years). The average BMI was 23 ± 3.7, ranging from 16 to 35. All patients were of Asian ethnicity. Based on the echo reports, 65 patients (64%) had normal LV function, 28 (28%) had mildly or moderately impaired LV function, and 8 (8%) had severely impaired LV function. 65 patients (64%) had LV hypertrophy; LV size was reported as dilated for 11 patients (11%). Regional wall motion abnormalities (RWMA) were indicated for 34 (33%) of the patients. The Specificity, sensitivity, accuracy and Pearson correlation were calculated. The analysis summary is provided in the table below:

Parameter	Second Validation Set

Specificity	82%
Sensitivity	82%
Accuracy	82%
Correlation	0.856
n	78

Specificity, Sensitivity accuracy and correlation between automated results and ground truth running on the second clinical validation set.

8. *Conclusion:* The intended use and the technological characteristics in the current device are the same as those in the predicate device. Likewise, the modifications do not affect the safety and effectiveness of the device. The performance tests have been completed and successfully verify the validated performance of the subject device. Therefore, DiA Imaging Analysis has concluded the LVivo Software Application is substantially equivalent to the predicate device.