March 6, 2025

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

Re: K243331
Trade/Device Name: LVivo Seamless
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: February 13, 2025
Received: February 13, 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,

for

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

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)*

K243331

Device Name

LVivo Seamless

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 of patients and Age >18.

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.

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510(k) Summary K243331

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:	March 6, 2025
2.	***Device & Classification Name:***	Medical Image Management and Processing System – classified as Class 2 QIH, Regulation Number 21 CFR 892.2050 LVivo Seamless
3.	***Predicate Device:***	K212466 LVivo Seamless
4.	***Description:***	The LVivo Seamless is a standalone application that extends the LVivo Platform and runs offline on a server in a healthcare environment. The system accepts echo examinations in DICOM format that are sent from an Ultrasound device and automatically selects the adequate clips for EF and GLS evaluation. After the clip selection, the LVivo Seamless activates the FDA cleared LVivo EF and LVivo Strain modules which perform automatic EF and Strain evaluation or EF and Strain analysis by FDA cleared 3rd party software. The results are sent to the PACS and are evaluated by a healthcare professional.
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.
6.	***Comparison of Technological Characteristics:***	The difference between the subject device and the predicate device is that in addition to the ability to use LVivo EF and LVivo Strain for automated EF and Strain analysis, it is now includes the ability to use Automated EF and automated Strain analysis by another FDA cleared 3rd party software. With respect to technology and intended use, DiA's LVivo Seamless is substantially equivalent to its predicate device. Based upon the outcomes from the risk analysis and Performance Testing Evaluation, DiA believes that the modification of the predicate device does not raise additional safety of efficacy concerns. The following comparison table depicts the changes.

	Submitted Device	**Predicate Device**
Features/Characteristics	**LVivo Seamless**	**LVivo Seamless**
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.	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.
Modules	same	LVivo EF and LVivo Strain
Automation	same	yes
Manual Adjustment	same	yes
Bi plane EF evaluation	same	yes
Simultaneous 2CH and 4CH evaluation	same	yes
Off-line EF evaluation using DICOM clips of any vendor	same	yes
Automated 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 EF	same	yes
Automated rejection of false results	same	yes
Volume calculation by standard Simpson's method of discs	same	yes
Volume curve calculation	same	yes
EF results presentation	same	yes
Enables calculation EF results for different cycle	same	yes
Algorithm	same	same
Calculation speed	same	yes
Capability or a part of a bigger package (device) for LV function evaluation	same	yes
Segmental Longitudinal Strain Measure	yes	yes
Global Longitudinal Strain (GLS) Measure	yes	yes
Operating System	Windows	Windows
Ability to activate 3rd party Auto EF and Auto Strain applications (TOMTEC)	yes	No
510(k) #	K243331	K212466

7. ***Performance Evaluation:***

The agreement between the device's output and the ground truth is comparable to the predicate device. A summary of the Performance Evaluation, which was based upon well-established test methods, demonstrated conformity to the intended use.
Success criteria:

1. 85% of the exams will be processed automatically based on correctly identified 4 chamber, 2 chamber and 3 chamber views
2. 80% correlation between the Ground Truth Biplane EF measurements and automated Biplane EF results.
3. 80% correlation between Ground Truth GLS measurements and automated GLS results

Total of 166 examinations were included in the validation:
71 exams acquired with EPIQ (Philips Healthcare). Age 61.0 ± 16.3, 53.5% male. BMI was 29.7 ± 6.6. 62.0% of the patients in this dataset were Black or African American. LV function was Normal in 64.8%. 7.0% of the patients had Mild LV dysfunction, 14.1% had Moderate LV dysfunction and 14.1% of the patients had severe LV dysfunction.

96 acquired with Vivid E95(74%), Vivid S70(12.5%), Vivid E9 (12%) (GE Healthcare). Average age was 64 ± 17 ranging from 25 to 92, 59% male. 51 patients (53%) had Normal LV systolic function, 45 patients (47%) had impaired LV function (21% severely impaired, 15% moderately impaired and 11% mildly impaired). For 90 patients (94%) BMI measurements were available and the average BMI was 26.6± 4.9, ranging from 17.8 to 45.4.

The analysis (e.g Pearson's Correlation and Bland Altman) results are provided for 139 exams (84%) in which the system correctly identified 4, 2 and 3 chamber views:

Measurement	Bland Altman: Mean, (LOA) (% points)	Data Range (% points)	Pearson's Correlation (r)
Biplane EF	1.22, (-8.49, 10.93)	8.8 – 73.6	0.95
GLS	-1.27 (-5.16, 2.62)	-3.35 - -25.41	0.92

8. ***Conclusion:***

The Intended Use and the technological characteristics in the current device are the same as those in the predicate device, including the addition of the ability to run TomTec Auto EF and Strain, do not affect the safety and effectiveness of the device. The performance tests have been completed and successfully support the device performance. Therefore, DiA Imaging Analysis concludes the LVivo Seamless is substantially equivalent to the predicate device.