December 9, 2021

DiA Imaging Analysis Ltd
% George Hattub
Senior Project Manager
Medicsense USA
291 Hillside Avenue
SOMERSET, MASSACHUSETTS 02726

Re: K212466
Trade/Device Name: LVivo Seamless v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 8, 2021
Received: November 10, 2021

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 (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/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,

For

Thalia T. Mills, Division Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
DiA 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 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.

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

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 https://www.upwork.com/freelancers/~0196e832ca4b82a2f3?viewMode=1
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:	December 7, 2021
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:***	K202546 LVivo Seamless (Reference Device K210053)
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 evaluation. 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:***	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	Reference Device
Features/Characteristics	**LVivo Seamless**	**LVivo Seamless**	**LVivo Software Application**
Product Code	same	QIH	QIH
Indication for Use	DiA's 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.	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
Modules	LVivo EF, LVivo Strain	LVivo EF	LVivo EF, LVivo SG (LVivo SWM & LVivo Strain), LVivo SAX, LVivo RV and LVivo Bladder
Automation	same	yes	yes
Manual Adjustment	same	yes	yes
Bi plane EF evaluation	same	yes	yes
Simultaneous 2CH and 4CH evaluation	same	yes	yes
Off-line EF evaluation using DICOM clips of any vendor	same	yes	yes
Automated ED and ES frames selection	same	yes	yes
Dynamic left ventricular	same	yes	yes
Manual editing by user capability	Same, added editing capabilities to the output results	yes	yes

Visually confirm EF	same	yes	yes
Automated rejection of false results	same	yes	yes
Volume calculation by standard Simpson's method of discs	same	yes	yes
Volume curve calculation	same	yes	yes
EF results presentation	same	yes	yes
Enables calculation EF results for different cycle	same	yes	yes
Algorithm	same	same	yes
Calculation speed	same	yes	yes
Capability or a part of a bigger package (device) for LV function evaluation	same	yes	yes
Segmental Longitudinal Strain Measure	yes	no	yes
Global Longitudinal Strain (GLS) Measure	yes	Yes (from LVivo EF module)	yes
GLS calculation per view	yes	no	no
Operating System	Windows	Windows	Windows/Linux (with Android option for LVivo EF
510(k) #	K212466	K202546	K210053

7. ***Performance Evaluation:***

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

1. Correct identification of 4ch and 2ch and 3ch views in 90% of the examinations

2. Correlation of 80% between GLS by AFI and GLS by LVivo Seamless

100 patient examinations were used for the validation. Inclusion criteria: Age>18, examinations in which GLS results by Automated Functional Imaging (AFI ,GE) were available. No exclusion criteria were applied. The system was able to recognize all three 4CH, 2CH and 3CH clips in 95% of the examinations. The measurements by LVivo Strain running offline on the automatically selected clips were compared to the measurements done routinely in the Echo lab by AFI. The GLS by LVivo Strain was compared to GLS by AFI. Statistical analysis was done by Correlation, Bland-Altman:

Measurement	Accuracy (Mean±1.96STD)	Data Range	Correlation
GLS	-1.4% ± 3.93%	-4% - -24%	0.88

sensitivity and specificity and of 0.90, and 0.83 respectively. The Normal\Abnormal threshold used for GLS was -18%

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 GLS Module, 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.