DiA Imaging Analysis Ltd.
℅ Mr. George J. Hattub
Senior Project Manager
Medicsense USA
291 Hillside Avenue
SOMERSET MA 02726

February 5, 2021

Re: K210053
Trade/Device Name: LVivo Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: December 31, 2020
Received: January 8, 2021

Dear Mr. 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, Ph.D.
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)*
K210053

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.

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

K210053

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:	January 27, 2021
2.	***Device & Classification Name:***	Automated Radiological Imaging Processing Software - classified as Class 2 QIH, Regulation Number 21 CFR 892.2050 LVivo Software Application
3.	***Predicate Device:***	K200232 LVivo Software Application
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. The global LV function is evaluated from two of the apical views: four-chamber (4CH) and two-chamber (2CH) by ejection fraction (EF). The segmental LV function is done from three apical views 4CH, 2CH and three chamber (3CH) and supports wall motion evaluation and strain. The LVivo platform supports also global and segmental evaluation of the LV from the parasternal short axis (SAX) view. 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.
5.	***Intended 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
6.	***Comparison of Technological Characteristics:***	With respect to technology and intended use, DiA's LVivo Software Application 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 Software Application**	**LVivo Software Application**
Product Code	same	QIH
Indication for Use	same	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	same	LVivo EF, LVivo SG, LVivo SAX, LVivo RV & LVivo Bladder
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	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 Presentation	same	yes
EF results presentation	same	yes
Enables presentation EF results for different cycle	same	yes
Algorithm	Modified in LVivo EF	yes
Calculation speed	same	yes
Capability or a part of a bigger package (device) for LV function	same	yes
Segmental Longitudinal Strain Measure	same	yes
Global Longitudinal Strain Measure	same	yes
Segmental wall motion evaluation	same	yes
Operating System	same	Windows/Linux (with Android option for LVivo EF
510(k) #	Pending	K200232

7. ***Performance Evaluation:***

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

A data set of 100 ambulatory and hospitalized patients referred for routine transthoracic echocardiography was previously collected according to GCP standards. The population was comprised of 59% male, mean age of 60.6 ±17.727. Inclusion criteria: age >18 in sinus rhythm without multiple premature beats. Patients with LBBB were excluded from the study. 27 patients had normal LV and 47 patients had coronary artery disease (CAD) function. Total of 96 examinations were used for the EF analysis (due to missing ref).

Acceptance criteria for EF analysis: biplane EF correlation >=80%, similar or better EF biplane results in terms of correlation, specificity, sensitivity, and kappa with respect to subject device.

For SWM and GLS analysis, a total of 98 examinations were used from the same data set (due to missing ref).

For GLS acceptance criteria: cutoff value < -17, Sensitivity>=75% compared to ref WSMI, similar or better results compared to subject device

For SWM acceptance criteria: Sensitivity >=75%, similar or better results compared to subject device

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 neural network, 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 Software Application is substantially equivalent to the predicate device.