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

May 24, 2024

Re: K240769
Trade/Device Name: LVivo IQS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 3, 2024
Received: May 3, 2024

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.

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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: 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)*

K240769

Device Name

LVivo IQS

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. 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

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 19, 2024

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

3. ***Predicate Devices:*** LVivo IQS K222970

4. ***Description:*** The LVivio IQS is an extension to the LVivio IQS (K222970), as an additional Algorithm with API that will be able to provide a Quality Score in real time to the Right Ventricle from the 4-chamber apical view of the heart. In addition, the LVivo IQS will be provided as a software component to be integrated by another computer programmer into their legally marketed ultrasound imaging device. Essentially, the Algorithm and API, which is a module, is a medical device accessory.

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. 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 IQS is substantially equivalent to its predicate device. Based upon the outcomes from the risk analysis and Performance Testing Evaluation, DiA believes that the incremental extension of the LVivo IQS module to the LVivo IQS predicate device does not raise additional safety of efficacy concerns. The following comparison table depicts the changes.

#	Features/ Characteristics	Submitted Device	Predicate Device K222970
		LVivo IQS	**LVivo IQS**
1	**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. In addition, it provides Quality Index Score Feedback.
2	**Product Code**	Same	QIH
3	**LVivo IQS Module**	LVivo IQS for LV from 4-Chamber View LVivo IQS for RV from 4-Chamber View	LVivo IQS for LV from 4-Chamber View
4	**Operating System**	Same	Ram: 8 GB Windows 10 or higher Processor: Intel core i3 compatible or higher
5	**Automated IQS**	Same	Yes
6	**Algorithm**	AI based	AI Based
7	**Grading system ranges**	Same	0-60% poor (red), 60-80 % medium (orange) 80-100 % good (green)
8	**I/O support through API**	yes	yes
9	**User group**	same	same
10	**510(k) #**	K240769	K222970

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

1. The performance of the LVivo IQS system was validated using already data acquired with different ultrasound devices and various cardiac pathologies, compared to quality tagging by experienced sonographer.

Success criteria:
Overall agreement of 75% between the LVivo IQS results and the data tagging by experienced sonographers

100 patient examinations were used for the validation. Inclusion criteria: Age>18, patients referred to routine Echo examination. Exclusion criteria: Subjects who fail to meet any inclusion criteria. A total of 49,623 frames were analyzed.

The overall agreement was agreement between the LVivo IQS (RV) and quality tagging by the experienced sonographers was 77%

2. The performance of the LVivo IQS system was validated using data acquired after using the LVivo IQS in real time while scanning the RV from the 4CH apical view. The scans were acquired in the Point of Care environment by medical doctors in their internship. The obtained quality score was documented before saving the clip. The ACEP score (1-5) and the obtained quality score by LVivo IQS were documented.

Success criteria: a. 80% of the saved Exams with image quality ACEP score 3-5, received at least “Medium” image quality by LVivo IQS.
b. 90% of these cases were clinically interpretable by the majority of three expert cardiologists specializing in echo.

182 patients were included in the study and the saved scans were analyzed. Inclusion criteria: Age >18, indication for POCUS, Exclusion criteria: subjects who fail to meet any inclusion criteria. The results are summarized in Table-1:

End point number	Results
a.	In 85% of the patients with image quality 3-5 by visual estimation it was possible to obtain at least “Medium” quality score by LVivo IQS
b.	92% of the above saved clips were clinically interpretable

Table-1: Results summary

8. ***Conclusion:*** The Intended Use and the technological characteristics of the subject device are the same as those in the LVivo IQS predicate device, and do not affect the safety and effectiveness of the device. The performance testing has been completed and has successfully verifed the performance of the device. Therefore, DiA Imaging Analysis concludes the LVivo IQS is substantially equivalent to the predicate device.