DiA Imaging Analysis Ltd.
% George Hattub
Senior Project Manager
Medicsense USA LLC
291 Hillside Avenue
SOMERSET MA 02726

February 1, 2023

Re: K222970
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: December 20, 2022
Received: December 21, 2022

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
and Radiation Therapy Devices
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K222970

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.

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# 510(k) Summary K222970

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


| | | |
|---|---|---|
| **1. (a)** | **Submitter Address:** | George J. Hattub<br>Medicsense USA LLC<br>291 Hillside Avenue<br>Somerset, MA 02726<br>ghattub@comcast.net |
| **1. (b)** | ***Manufacturer Address:*** | DiA Imaging Analysis Ltd<br>HaEnergia Street 77<br>Beer-Sheva, Israel 8470912 |
| | ***Mfg. Phone:*** | Tel.: +972 77 7648318 |
| | ***Contact Person:*** | Mrs. Michal Yaacobi |
| | ***Date:*** | December 20, 2022 |
| **2.** | ***Device & Classification Name:*** | Medical Image Management and Processing System – classified as Class 2 QIH, Regulation Number 21 CFR 892.2050<br>LVivo IQS |
| **3.** | ***Predicate Devices:*** | LVivo Software Application K210053 |
| **4.** | ***Description:*** | The LVivio IQS is an extension to the LVivio Software Application (K210053), as an additional Algorithm with API that will be able to provide a Quality Score in real time to the Left 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, will be a medical device accessory. The QIS Meter concept is similar to the legally marketed Caption Guidance Software Device. |
| **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 devices. Based upon the outcomes from the risk analysis and Performance Testing Evaluation, DiA believes that the extension of LVivo IQS module to 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 K210053 |
|---|---|---|
| **Features/ Characteristics** | **LVivo IQS as an addition to the 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. 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. |
| **Modules** | LVivo IQS, LVivo EF, LVivo SG, LVivo SAX, LVivo RV & LVivo Bladder | 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 LV RV and Bladder evaluation using DICOM clips of any vendor** | same | yes |
| **Automated ED and ES frames selection** | 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 EF** | same | yes |
| **Volume\Area curve Presentation** | same | yes |
| **EF, Strain, SWM, RV, SAX, Bladder results presentation** | same | yes |
| **Enables presentation cardiac function results for different cycle** | 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** | same | yes |
| **Operating System** | same | Windows/Linux (with Android option for LVivo EF) |
| **Quality score feedback** | Yes | No |
| **510(k) #** | Pending | K219953 |

**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. Total of 22,663 frames were analyzed.

The overall agreement was agreement between the LVivo IQS and quality tagging by the experienced sonographers was 81%

2. The performance of the LVivo IQS system was validated using data acquired after using the LVivo IQS in real time while scanning the LV from the 4CH apical view. The scans were done by POC interns in POC environment. The obtained quality score before saving a clip was recorded.

Success criteria: a. 80% of the saved Exams with image quality 3-5 by visual estimation, received at least “Medium” image quality by LVivo IQS.
b. 90% of these cases are clinically interpretable by expert echocardiologist

64 patients were included in the study and the saved scans were analyzed. Inclusion criteria: Age ≥18, indication for POCUS, image quality 3-5 according to ACEP Guidelines, Exclusion criteria: subjects who fail to meet any inclusion criteria, image quality 1-2 according to ACEP Guidelines. The results are summarized in Table-1:

| End point number | Results |
|---|---|
| a. | In 90% 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. | 93% of the above saved clips were clinically interpretable |

Table-1: Results summary

**8.** ***Conclusion:*** The Intended Use and the technological characteristics in the current device are the same as those in the LVivo software application predicate device, including the addition of the IQS 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 IQS is substantially equivalent to the predicate device.