September 26, 2025

Ligence, UAB
% Raymond Kelly
Consultant
Arazy Group Consultants Inc.
3422 Leonardo Lane
New Smyrna Beach, Florida 32168

Re: K252105
Trade/Device Name: Ligence Heart
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 5, 2025
Received: September 5, 2025

Dear Raymond Kelly:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252105

Please provide the device trade name(s).

Ligence Heart

Please provide your Indications for Use below.

Ligence Heart is a fully automated software platform that processes, analyses and makes measurements on acquired transthoracic cardiac ultrasound images, automatically producing a full report with measurements of several key cardiac structural and functional parameters. The data produced by this software is intended to be used to support qualified cardiologists or sonographers for clinical decision making. Ligence Heart is indicated for use in adult patients. Ligence Heart has not been validated for the assessment of congenital heart disease, valve disease, pericardial disease, and/or intra-cardiac lesions (e.g., tumors, thrombi).

Limitations:

- Poor image capture will lead to poor annotations and subsequent measurements.
- Multiple image quality algorithms are used to filter out images of poor quality.
- Our software complements good patient care and does not exempt the user from the responsibility to provide supervision, clinically review the patient, and make appropriate clinical decisions.
- If no gender is present, female referenced guideline values will be used for conclusions.
- If Body Surface Area (BSA) is not present, indexed values cannot be provided.
- During image acquisition, inappropriate use of the echo machine, use of non-cardiac ultrasound probes, or use of suboptimal settings (e.g., gain, contrast, depth) may lead to lower accuracy of the software.
- Ligence Heart has not been validated in patients with prosthetic or surgically altered cardiac valves, implantable intracardiac devices, or irregular (non-sinus) rhythm; these conditions may affect automated measurement accuracy.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
21 CFR 807.92

K252105

I. SUBMITTER (21 CFR 807.92(a)(1))

Submitter: Ligence, UAB
Taikos pr. 54 Kaunas,
51305, Lithuania

Phone: +37061144345

Contact Person: Alvaro Perez-Moreno, Ph.D.

Date Prepared: July 2, 2025

II. DEVICE (21 CFR 807.92(a)(2))

Name of Device: Ligence Heart
Common or Usual Name: Automated Radiological Image Processing Software
Classification Name: Medical Image Management and Processing System (§892.2050)
Regulatory Class: II
Product Code: QIH

III. PREDICATE DEVICE (21 CFR 807.92(a)(3))

Us2.vl, K210791
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION (21 CFR 807.92(a)(4))

Ligence Heart is an image post-processing software used for viewing and quantifying adult cardiac ultrasound DICOM studies. The device is intended to generate structured measurement reports for echocardiography analysis and aid qualified sonographers and cardiologists in their decision-making process.

Ligence Heart automatically identifies standard transthoracic echo views with machine-learning–based view classification, cardiac cycle selection, and border detection, then

generates reproducible quantitative left-ventricular volumetric and functional measurements. The results are inserted into a PACS-compatible report that the reviewing cardiologist or sonographer can accept, edit, supplement with additional manual measurements, or entirely replace with manual measurements. The software also organizes, displays, and compares each measurement with reference-guideline ranges. Completed reports are exported in PDF, streamlining routine echocardiography workflow while leaving final diagnostic responsibility with the clinician.

V. INDICATIONS FOR USE (21 CFR 807.92(a)(5))

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE (21 CFR 807.92(a)(5) & 21 CFR 807.92(a)(6))

Attribute	Predicate Device: K210791	Subject Device
Product Code	QIH	QIH
Regulation	892.2050	892.2050
Classification	II	II
Rx/OTC	Rx	Rx
Physical Characteristics	Software package that operates utilizing off-the-shelf hardware	Software package that operates utilizing off-the-shelf hardware
User interface	The software is designed for use on a personal computer that has received images from a compatible PACS	The software is designed for use on a personal computer that has received images from a compatible PACS
Automation level	Fully automated, including clip selection	Fully automated, including clip selection
User confirmation / rejection of result	Yes	Yes
Manual editing of automated result by user	Yes	Yes
Input Data	Echocardiographic images	Echocardiographic images
Communication protocol	DICOM Standard Compliance	DICOM Standard Compliance
Patient Populations	Adults	Adults

Both the subject and predicate devices share the following technological characteristics:

Variations in automated-measurement implementation:
Ligence Heart automatically generates four core left-ventricular measurements essential for efficient and accurate routine cardiac assessments: lateral mitral-annular early-diastolic velocity (lateral e', Le), left-ventricular end-diastolic volume by the biplane Method of Disks (LVEDV MOD), left-ventricular ejection fraction by the biplane Method of Disks (LVEF MOD), and left-ventricular end-systolic volume by the biplane Method of Disks (LVESV MOD).

VII. PERFORMANCE DATA (21 CFR 807.92(b))

Ligence Heart was developed and tested in accordance with Ligence Heart's life cycle development processes. The device has been subject to extensive safety and performance testing. Verification and validation test results established that the device meets its design requirements and intended use. Specifically, software verification was conducted at the unit, integration, and system levels. Risk management analysis generated multiple risk mitigation measures and verification activities. A cybersecurity analysis and testing were conducted to verify that security measures are properly implemented in Ligence Heart to protect Ligence Heart's data, including patient health information (PHI). A summative human factors study was performed to validate that Ligence Heart can be used safely and effectively by the intended user population.

A formal retrospective non-interventional validation study was conducted at a U.S. based independent Echocardiography Core Laboratory using 600 previously acquired echocardiograms to evaluate the performance of the device for each claimed measurement. Test datasets were strictly segregated from algorithm training datasets, as they are from completely separate cohorts.

A cumulative total of 76 studies were excluded because of missing views or corrupt metadata. Ultimately, 524 echocardiographic studies were assessed by all three human readers, satisfied the predefined quality criteria, and were included in the final analysis. Baseline demographic characteristics of the cohort are summarized in the table below.

Participants characteristics	
Age, years	49.48 ± 13.56
Male, n (%)	319 (60.88%)
Female, n (%)	205 (39.12%)
Height, cm	173.36 ± 10.52
Weight, kg	88.92 ± 21.11
LVEF, %	34.45% ± 15.78%
Normal LVEF (>50%), n (%)	120 (22.90%)
Reduced LVEF (<50%), n (%)	404 (77.10%)

Participants characteristics	
Mildly reduced LVEF (40-50%), n (%)	64 (12.21%)
Moderately reduced LVEF (30-40%), n (%)	85 (16.22%)
Severely reduced LVEF (<30%), n (%)	255 (48.66%)

Primary Clinical Performance Endpoint was Individual Equivalence Coefficient (IEC). Agreement between Ligence Heart and three independent expert sonographers was quantified using the reference-scaled IEC. Automated measurements are deemed interchangeable when the upper level of the IEC 95% confidence interval was < 0.25, a non-inferiority margin derived from individual-bioequivalence principles.

All four parameters met the non-inferiority criterion, confirming that Ligence Heart measurements are interchangeable with expert human measurements. Secondary agreement metrics were consistent with the IEC result. Intraclass Correlation Coefficients (ICC) were ≥ 0.90 for all four parameters. No device-related adverse events, malfunctions, or unmediated issues occurred during the study.

These combined non-clinical and clinical data demonstrate that Ligence Heart satisfies its specified performance criteria and support determination of substantial equivalence.

VIII. CONCLUSIONS (21 CFR 807.92(b))

Ligence Heart is substantially equivalent to the predicate device Us2.v1 (K210791). The subject and predicate share the same intended use, core technological characteristics, and fundamental principles of operation. No distinctions between the two systems do not introduce new questions of safety or effectiveness.

Comprehensive non-clinical testing, including software verification and validation, cybersecurity assessment, and summative human-factors validation, demonstrated that the software platforms as intended and can be used safely under the specified conditions. Complementary clinical validation confirmed that automated measurements of LVEF, LVEDV, LVESV, and lateral e′ are interchangeable with expert manual measurements and remain within normal inter-observer variability.

Taken together, the non-clinical and clinical data show that Ligence Heart is at least as safe and effective as the predicative device for post processing analysis of adult transthoracic echocardiograms.