Viz.ai, Inc.
℅ Vi Ma
Regulatory Affair Specialist
201 Mission Street, 12th Floor
SAN FRANCISCO CA 94105

August 29, 2022

Re: K221100
Trade/Device Name: Viz RV/LV
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: August 4, 2022
Received: August 5, 2022

Dear Vi Ma:

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 Imaging Devices
and Electronic Products
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K221100

Device Name

Viz RV/LV

Indications for Use *(Describe)*

The Viz RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. Viz RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the ventricles. The Viz RV/LV software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.

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-K221100

Viz.ai, Inc.'s Viz RV/LV

Applicant Name: Viz.ai, Inc.
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Date Prepared: August 24, 2022

Device Name and Classification

Name of Device: Viz RV/LV

Common or Usual Name: Automated Radiological Image Processing Software

Classification Panel: Radiology

Regulation No: 21 C.F.R. § 892.2050

Regulatory Class: Class II

Product Code: QIH

Predicate Device

Manufacturer	Device Name	Application No.
Imbio	Imbio RV/LV Software	K203256

Device Description

The Viz RV/LV is a software-only device that uses a locked artificial intelligence machine learning (AI/ML) algorithm to measure the maximal diameters of the right and left ventricles of the heart from a computed tomography pulmonary angiogram (CTPA) and report the ratio of those measurements.

Viz RV/LV produces an Annotated Image Series **(Figure 1)** and an RV/LV Summary Report **(Figure 2)** in DICOM format. The Annotated Image Series shows an RGB overlay on each slice of the input scan:

- The red and blue solid lines indicate the maximum ventricular diameter for each ventricle.
- The dashed line indicates a diameter measured on a slice that is within 10 slices of the global maximum ventricular diameter.

- The interventricular septum is marked in solid green on all images where diameters are marked.
- The maximal diameter is presented along with solid lines on slices with global maximum diameter.

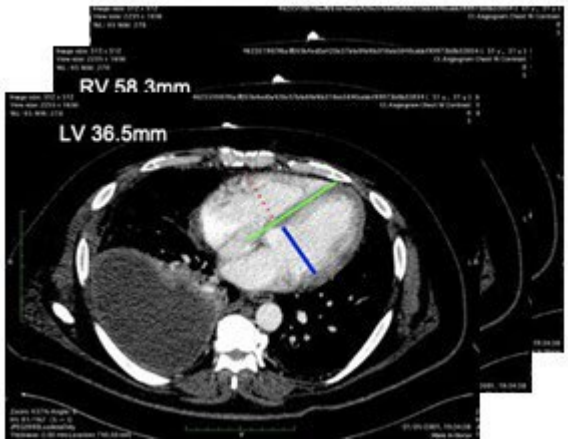

Figure 1: Annotated Image Series

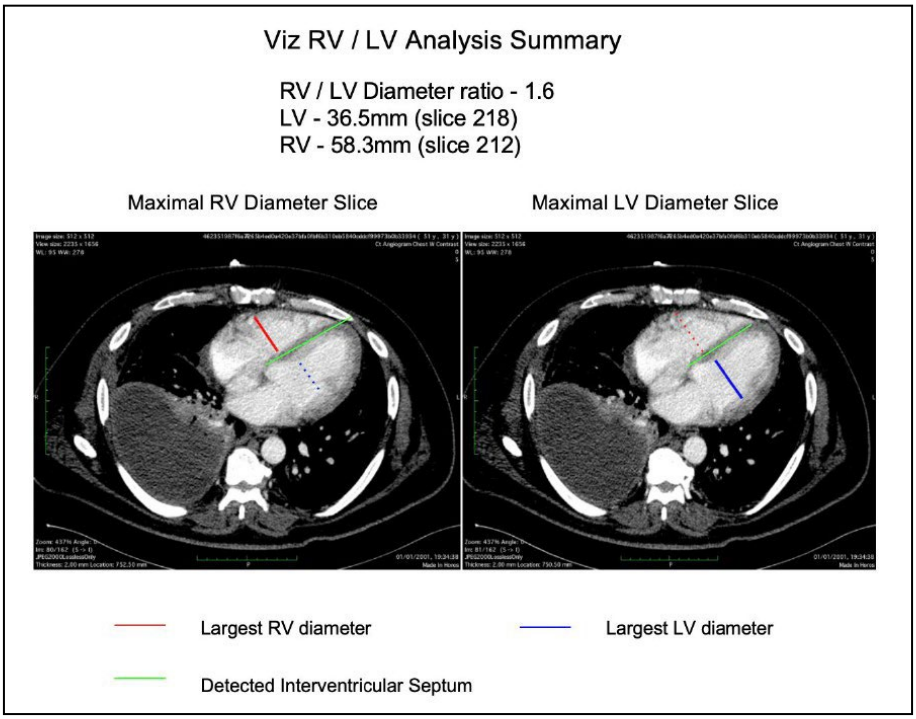

Figure 2: RV/LV Summary Report

The RV/LV Summary Report summarizes the results of the ventricle analysis and shows the slices with the maximum right and left ventricular diameters. The lines measuring the maximum RV and LV

diameters are displayed over the original CTPA slice image, along with the lengths of the largest RV and LV diameters, and the RV/LV ratio.

Viz RV/LV is hosted on Viz.ai's Backend Server and analyzes applicable CTPA scans that are acquired on CT scanners and are forwarded to Viz.ai's Backend Server. The results of the analysis are exported in DICOM format are sent to a PACS destination for review by thoracic radiologists, general radiologists, pulmonologists, cardiologists, or other similar physicians to assist in the assessment of right ventricle enlargement. The basic principle of operations is outlined in **Figure 3** below.

Figure 3. Data and Event Workflow

Intended Use / Indications for Use

Viz.ai RV/LV software and the predicate device, Imbio RV/LV software (K203256), are *Medical Image Management and Processing System* software intended to calculate of the ratio of right ventricular diameter to left ventricular diameter from contrast enhanced CT images of the chest acquired using a standard CT pulmonary angiogram acquisition.

Viz RV/LV has the following indications for use:

> The Viz RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. Viz RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the ventricles. The Viz RV/LV software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.

The predicate device, Imbio RV/LV Software (K203256), has the following indications use:

> The Imbio RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the ventricles. The RV/LV

software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.

In comparing the intended use and indications for use of Viz RV/LV and the predicate device, Viz RV/LV has the same intended use as its predicate device.

A substantial equivalence chart (**Table 1**) comparing the subject device, Viz RV/LV, and the predicate, the Imbio RV/LV software, is provided below:

Table 1 Technological Characteristic Comparison

	Predicate Device **Imbio RV/LV Software**	**Subject Device** **Viz RV/LV**
Device Class	2	2
Product Code	QIH	QIH
Regulation Number:	21 C.F.R. § 892.2050	21 C.F.R. § 892.2050
Indications for Use:	The Imbio RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the ventricles. The RV/LV software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.	The Viz RV/LV Software device is designed to measure the maximal diameters of the right and left ventricles of the heart from a volumetric CTPA acquisition and report the ratio of those measurements. Viz RV/LV analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the ventricles. The Viz RV/LV software provides the user with annotated images showing ventricular measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CTPA cases.
Input Data Requirements:	Non-gated, CT Pulmonary Angiography (CTPA)	Same
DICOM Compliant	Yes	Same
Left Ventricle Segmentation	Yes	Same
Right Ventricle Segmentation	Yes	Same
Diameter Measurements	Yes – Automated	Same
Fully automated segmentation	Yes	Same
Outputs	Reports, DICOM Secondary Capture Series	Same

Performance Data

Clinical testing was performed as a study comparing the Viz RV/LV's output to the ground truth as established by trained radiologists. There was a high degree of agreement between the different trained radiologist as demonstrated by statical analysis. The study demonstrated that the MAE (Mean absolute error) was less than 7.2 mm between the algorithm and the established ground truth, which was aligned with the performance goal.

Additional statistical analysis was performed to describe the degree of agreement between the ventricle diameters measured by the RV/LV algorithm in comparison to the measurements that were obtained manually. The algorithm's ventricle diameter measurements were aligned when compared against the measurements that were obtained manually.

Stratification of device performance was divided by clinical site, gender, age, slice thickness, scanner manufacture and model.

The 4 clinical sites used in the pivotal study were a subset of a larger 13 sites used as part of the training data set. There was no overlapping data between the training sets and the pivotal study in terms of time and patient images.

Conclusions

A comparison of intended use and technological characteristics, along with clinical performance data, demonstrated that the device is as safe and effective as the previously cleared Imbio RV/LV software (K203256). Thus, Viz RV/LV is substantially equivalent to Imbio RV/LV.
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