iSchema View Inc.
℅ James Rosa
SVP Regulatory and Quality
433 Park Point Drive, Suite 220
GOLDEN CO 80401

Re: K223396 February 1, 2023
Trade/Device Name: Rapid RV/LV
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: December 27, 2022
Received: December 27, 2022

Dear James Rosa:

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.

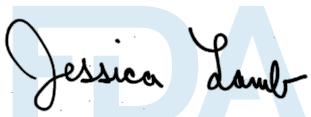
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223396

Device Name
Rapid RV/LV

Indications for Use *(Describe)*
The Rapid 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 for adults. Rapid RV/LV analyzes cases using machine learning algorithms to identify locations and measurements of the ventricles. The Rapid RV/LV device 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.**

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.***

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**510(k) Summary**

**iSchemaView, Inc.'s Rapid RV/LV**

This document contains the 510(k) summary for the iSchemaView Rapid RV/LV device. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

**Applicant Name and Address:**

| | |
|---|---|
| **Name:** | iSchemaView, Inc. |
| **Address:** | 1120 Washington St., Suite 200<br>Golden, CO 80401 |
| **Official Contact:** | Jim Rosa<br>Phone: (303) 704-3374<br>Email: rosa@ischemaview.com |

**Summary Preparation Date:** January 31, 2023

**Device Name and Classification:**

| | |
|---|---|
| **Trade Name:** | Rapid RV/LV |
| **Common Name:** | Automated Radiological Image Processing Software |
| **Classification:** | II |
| **Product Code:** | Primary: QIH |
| **Regulation No:** | 21 C.F.R. §892.2050 |
| **Classification Panel:** | Radiology Devices |

**Predicate Devices:**

The iSchemaView Rapid RV/LV Analysis Module is claimed to be substantially equivalent to the following legally marketed predicate devices:

Imbio's RV/LV Software (K203256)

**Device Description:**

Rapid RV/LV software device is a radiological computer-assisted image processing software device. The Rapid RV/LV device is a CTPA processing module which operates within the integrated Rapid Platform to locate and measure the right and left ventricle diameters of the human heart to ultimately provide a ratio of the right ventricle diameter to the left ventricle diameter. The RV/LV software analyzes input CTPA images that are provided in DICOM format and provides both a visual output containing a color overlay image displaying where the ventricle diameter measurements were made along with the quantitative results of the measurements and a text file output (json format) containing the quantitative measurement results (the individual right and left ventricle diameters and their corresponding ratio).

510(k) Summary

**Indications for Use:**

The Rapid 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 for adults. Rapid RV/LV analyzes cases using machine learning algorithms to identify locations and measurements of the ventricles. The Rapid RV/LV device 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.

**Technological Characteristics and Substantial Equivalence:**

Rapid RV/LV does not raise new questions of safety or effectiveness compared to the previously cleared Imbio RV/LV Software (K203256). There are minor differences in intended use and technical characteristics with the predicate device; however, with the minor changes the clinical use for Rapid RV/LV device is the same with no additional risks. Thus, the Rapid RV/LV software device is substantially equivalent.

The following table summarizes and compares data on the Imbio RV/LV Software (K203256) to the Rapid RV/LV software device that is the subject of this Traditional 510(k) submission.

| Parameter | Imbio RV/LV Software K203256 - Predicate Device | Rapid RV/LV – Subject Device K223396 |
|---|---|---|
| Product Code | QIH | QIH |
| Regulation | 21 CFR §892.2050 | 21 CFR §892.2050 |
| Intended Use/ 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 Rapid 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 for adults. Rapid RV/LV analyzes cases using machine learning algorithms to identify locations and measurements of the ventricles. The Rapid RV/LV device 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 | Same |

| | | |
|---|---|---|
| | Angiography images | |
| DICOM Compliance | Yes, using CTPA | Same |
| LV Segmentation | Yes | Same |
| RV Segmentation | Yes | Same |
| Diameter Measurements | Yes – Automated | Same |
| Fully Automated Segmentation | Yes | Same |
| Interface | Command Line | Command Line |
| Outputs | Reports, DICOM Secondary Capture Series | Reports, DICOM Secondary Capture Series |

**AI/ML Module Development:**

Algorithm development was performed using 516 CTPA cases from multiple sites; training included 80% of cases for validation and 20% for training. Cases selected covered a wide range of LV diameters. Cases were obtained from Siemens, GE, Toshiba, and Philips scanners.

**Clinical Characteristics:**

The primary users of Rapid RV/LV software are medical professionals who use RV/LV ratio as a clinical metric quantifying the severity of right-heart strain.

**Performance Standards:**

Rapid PE has been developed in conformance with the following standards, as applicable:

| | |
|---|---|
| EN ISO 14971:2019 (R2021) | Application of Risk Management to Medical Devices |
| IEC 62304:2006 (R2015) | Medical device software – Software lifecycle processes |
| IEC 62366:2015 (R2020) | Application of Usability Engineering to Medical Devices |
| NEMA PS 3.1 - 3.20 | Digital Imaging and Communications in Medicine (DICOM) |

**Performance Data:**

Rapid RV/LV complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. NEMA PS 3.1 - 3.20.

iSchemaView conducted extensive performance validation testing and software verification and validation testing of the Rapid RV/LV device. Final device validation included standalone performance validation. This performance validation testing demonstrated the Rapid RV/LV device provides accurate representation of key processing parameters under a range of clinically relevant perturbations associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Rapid RV/LV device met all design requirements and specifications.

510(k) Summary

Final performance validation included 124 CTPA cases with ground truth established by 3 experts. The primary endpoint passed, the average slope was 1.1 (95% CI: 1.0, 1.2) and the average intercept was -0.2 (95% CI: -0.1, -0.3 The lower confidence level of the 95% CI of the slope and intercept were 1.0 and -0.1. The secondary endpoint (Bland-Altman bias) passes with mean bias of 0.023 (95% CI 0: -0.04, 0.08). Mean Absolute Error (MAE) between Rapid RV/LV and the experts was calculated at 3.8mm. The cases were split Male: 44%, Female 56% with an age range or 26-93 years. The samples were mixed from GE, Philips, Toshiba and Siemens scanners.

**Prescriptive Statement:**
Caution: Federal law restricts this device to sale by or on the order of a physician.

**Safety & Effectiveness**:
Rapid RV/LV has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with EN ISO 14971:2019 (risk management). The Rapid RV/LV performance has been validated with case data.

**Conclusion:**

In conclusion, the iSchemaView Rapid RV/LV software device is substantially equivalent in intended use, technological characteristics, safety and performance characteristics to the legally marketed predicate device, Imbio RV/LV Software (K203256).