Imbio, LLC
% Mr. William McLain
Manager, RA/QA
1015 Glenwood Avenue, Floor 4
MINNEAPOLIS MN 55405

March 9, 2021

Re: K203256
Trade/Device Name: Imbio RV/LV Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: February 4, 2021
Received: February 5, 2021

Dear Mr. McLain:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K203256

Device Name

RV/LV Software

Indications for Use *(Describe)*

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.

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."

I 510(k) Summary - K203256

I.1 Submission Owner and Correspondent

Imbio, LLC
1015 Glenwood Avenue
Floor 4
Minneapolis, MN 55405
Contact: William McLain
Phone: 717-656-9656
E-Mail: billmclain@imbio.com

Other submissions correspondents:
Lauren Keith, Director of Engineering, and
Hatice Akakin, Machine Learning Specialist

I.2 Date Summary Prepared

February 1, 2021

I.3 Device Trade Name

RV/LV Software

I.4 Device Common Name

Automated Radiological Image Processing Software

I.5 Device Classification Name

Picture archiving and communications system. Classified as Class 2 at 21 CFR 892.2050, product code QIH.

I.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The RV/LV Software is substantially equivalent to the ct[42] Cardiac Computed Tomography Software cleared under K111373.

I.7 Description of the Device

The Imbio CT RV/LV Software is a set of medical image post-processing computer algorithms that together perform automated image segmentation and diameter measurements on computed tomography pulmonary angiography (CTPA) images. The device then reports the ratio of those diameter measurements. The Imbio CT RV/LV Software is a single

command-line executable program that may be run directly from the command-line or through scripting and thus the user interface is minimal.

Imbio RV/LV Software is a Software and Medical Device (SaMD) intended to provide annotated images and a PDF report that will be read most typically at a PACS workstation. Imbio RV/LV Software is an aid only used to support a physician in the analysis of CTPA images.

The Imbio RV/LV Software program reads in DICOM CPTA image datasets, processes the data, then writes output DICOM files and summary reports to a specified directory. Imbio RV/LV Software outputs DICOMs of the original input DICOM CPTA images overlaid with color-codings representing the results of RV/LV computer caliper measurement. Additionally, a summary PDF report is output.

Imbio RV/LV Software does not interface directly with any CT scanner or data collection equipment; instead the software imports data files previously generated by such equipment and is integrated as part of the radiological work-flow, reducing the risk of use errors.

I.8 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.

I.9 Technological Characteristics

Table 5 compares the technological characteristics between the proposed RV/LV Software and the predicate ct[42] Cardiac Computed Tomography Software.

Table 5: Technological Characteristics Comparison

Feature	**Proposed Device - RV/LV Software**	**Predicate Device - ct[42] Cardiac Computed Tomography Software (K111373)**
510(k) #	TBD	K111373
Device Class	2	2
Product Code	QIH	LLZ
Regulation Name	Picture Archiving and communications systems	Picture Archiving and communications systems
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Indication for Use	Due to the length of the statement, see below.	Due to the length of the statement, see below.
Input Data Requirements	Non-gated, CT Pulmonary Angiography images	EKG-gated Cardiac CT images
DICOM Compliant	Yes	Yes
LV Segmentation	Yes	Yes
RV Segmentation	Yes	Yes
Diameter Measurements	Yes - Automated	Yes - Manual
Fully-automated segmentation	Yes	No
Interface	Command-Line	Graphical user interface
Outputs	Reports, DICOM Secondary Capture series	Report, DICOM Secondary Capture Series.

Proposed RV/LV Software Indication 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.

Predicate ct^{42} Cardiac Computed Tomography Software Indications for Use: ct^{42} is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables:

- Importing Cardiac CT Images in DICOM format
- Supporting clinical diagnostics by qualitative analysis of the cardiac CT images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases, 3D reconstruction of images including multi-planner reconstructions of the images.
- Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac CT images
- Supporting clinical diagnostics by quantitative measurements of calcified plaques in the coronary arteries (calcium scoring), specifically Agatston and volume and mass calcium scores

It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. ct^{42} is a software application that can be used as a stand-alone product or in a networked environment.

The target population for the ct^{42} is not restricted, however the image acquisition by a cardiac CT scanner may limit the use of the device for certain sectors of the general public.

ct^{42} shall not be used to view or analyze images of any part of the body except the cardiac CT images acquired from a cardiovascular CT scanner.

I.10 Non-Clinical Testing

Non-clinical testing was conducted in the form of a software validation.

I.11 Biocompatibility

Biocompatibility testing is not applicable for the RV/LV Software.

I.12 Clinical Testing

Clinical performance testing was conducted in the form of a reader study. In order to assess the software's clinical performance, two different evaluations were carried out. The first test plan (Reader Study-I) demonstrated the improvement of the agreement among general radiologist with the assistance of the RVLV output report. The second test (Reader Study- II) will demonstrated the accuracy of RVLV diameter ratios compared to radiologist's measurement of the RVLV diameter ratio. Anonymized CTPA datasets were utilized in the reader study.

I.13 Conclusions

The results of the comparison of design, intended use and technological characteristics demonstrate that the device is as safe and effective as the legally marketed predicate device.