Imbio, Inc
Lauren Keith
Director of Engineering
1015 Glenwood Ave
Floor 4
Minneapolis, Minnesota 55405

August 30, 2024

Re: K241847
Trade/Device Name: Imbio PHA (4.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 6, 2024
Received: August 6, 2024

Dear Lauren Keith:

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.

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,

Jessica Lamb

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241847

Device Name

Imbio PHA (4.0.0)

Indications for Use *(Describe)*

The Imbio PHA Software device is designed to measure the maximal diameters of the right and left ventricles of the heart, the main pulmonary artery, and the ascending aorta from a volumetric CTPA acquisition and report the RV/LV and Pa/Ao ratios. PHA analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the anatomy. The PHA software provides the user with annotated images showing 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) #: K241847

510(k) Summary

Prepared on: 2024-08-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Imbio, Inc
Applicant Address	1015 Glenwood Ave Floor 4 Minneapolis MN 55405 United States
Applicant Contact Telephone	608-213-7100
Applicant Contact	Dr. Lauren Keith
Applicant Contact Email	laurenkeith@imbio.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Imbio PHA (4.0.0)
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203256	Imbio RV/LV	QIH

Device Description Summary

21 CFR 807.92(a)(4)

Imbio's PHA Software is a set of medical image post-processing computer algorithms that together perform automated right and left ventricle, pulmonary artery (PA), and aorta (Ao) measurements from CT pulmonary angiography (CTPA) scans, and reports the RV/LV and PA/Ao ratios. The Imbio PHA 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 PHA Software is a Software as a Medical Device (SaMD) intended to provide annotated DICOM-formatted images and a PDF report that will be read most typically at a PACS workstation. Imbio PHA Software is an aid, only used to support a physician in the analysis of CTPA images.

The Imbio PHA Software program reads in CTPA DICOM datasets, processes the data, then writes output DICOM files and summary reports to a specified directory. Imbio PHA Software outputs DICOMs of the original input DICOM CT images overlaid with color-codings indicating where the measurements were made. Additionally, a summary PDF report is output.

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

100 contrast-enhanced CT pulmonary angiography (CTPA) datasets were used for standalone performance assessment. The datasets were sourced from multiple centers and multiple databases and included a range of convolution kernels (vendor equivalent of GE's Soft, Detail, Standard, and Standard Iterative kernels) and slice thicknesses (0.75 mm, 1.00 mm, 1.25 mm, 1.5 mm, and 2.00 mm) from the four major CT scanner vendors. The datasets are representative of the intended patients because they are all clinically indicated for a CTPA scan, which is primarily indicated for suspicion of pulmonary embolism or pulmonary hypertension.

Three expert, U.S. board-certified radiologists practicing within the United States were enrolled to perform ground truthing of the performance datasets. Each truther had a minimum of 10 years clinical experience. The ground truthing exercise consisted of each radiologist measuring the diameter of the pulmonary artery trunk at the level of the bifurcation and the aorta diameter at the same slice. Intra-class correlation coefficients were calculated to show equivalency. There were two acceptance criterion:

*ICC of all measurements (annotators and algorithm) > 0.90 (excellent)

*ICC of all measurements (annotators and algorithm) within 95% CI of the ICC of only annotators

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Imbio PHA Software device is designed to measure the maximal diameters of the right and left ventricles of the heart, the main pulmonary artery, and the ascending aorta from a volumetric CTPA acquisition and report the RV/LV and Pa/Ao ratios. PHA analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the anatomy. The PHA software provides the user with annotated images showing 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for Use differ slightly between the predicate and the proposed devices. The IFUs have been reworded slightly to include the main pulmonary artery and ascending aorta measurements. The overall intended use of the devices are equivalent: to use deep-learning models to measure diameters of clinically relevant cardiovascular structures from a CTPA image. The differences in IFU statements have no negative impact on safety or effectiveness because neither the predicate's nor the subject device's 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 Comparison 21 CFR 807.92(a)(6)

Proposed Device Characteristics
Name: Imbio PHA
510(k) Number: TBD
Product Code: QIH
Regulation Name: Picture Archiving and communications systems
Regulation Number: 21 CFR 892.2050
Input Data Requirements - General: Non-gated, CT Pulmonary Angiography images
DICOM compliant: Yes
LV Segmentation: Yes - Deep Learning
RV Segmentation: Yes - Deep Learning
mPA Segmentation: Yes - Deep Learning
Ao Segmentation: Yes - Deep Learning
Diameters Measurements: Yes - Automated
Fully-automated: Yes
Interface: Command-line
Ability to QA Results: Yes - via outputs
Outputs: Report, DICOM Secondary Capture series

Proposed Indications for Use: The Imbio PHA Software device is designed to measure the maximal diameters of the right and left ventricles of the heart, the main pulmonary artery, and the ascending aorta from a volumetric CTPA acquisition and report the RV/LV and Pa/Ao ratios. PHA analyzes cases using an artificial intelligence algorithm to identify the location and measurements of the anatomy. The PHA software provides the user with annotated images showing 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 Device Characteristics
Name: Imbio RV/LV
510(k) Number: K203256
Product Code: QIH
Regulation Name: Picture Archiving and communications systems
Regulation Number: 21 CFR 892.2050
Input Data Requirements - General: Non-gated, CT Pulmonary Angiography images
DICOM compliant: Yes
LV Segmentation: Yes - Deep Learning
RV Segmentation: Yes - Deep Learning
mPA Segmentation: No
Ao Segmentation: No
Diameters Measurements: Yes - Automated
Fully-automated: Yes
Interface: Command-line
Ability to QA Results: Yes - via outputs
Outputs: Report, DICOM Secondary Capture series

Predicate 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.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No clinical testing was conducted. The Imbio PHA Software provides quantitative metrics with well-known clinical value. Non-Clinical testing was conducted to ensure that the measurements provided by the PHA Software, specifically the PA and Ao diameters, resemble measurements of the same anatomy performed by radiologists. The ICC between three expert radiologists and the algorithm results is 0.94, indicating excellent agreement.

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective as Imbio RV/LV (K203256).