June 13, 2023

Imbio, Inc.
℅ Lauren Keith
Director of Engineering
1015 Glenwood Avenue, Floor 4
MINNEAPOLIS MN 55405

Re: K230112
Trade/Device Name: CAC Software
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 9, 2023
Received: May 9, 2023

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 (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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K230112

Device Name

CAC Software

Indications for Use *(Describe)*

Imbio CAC Software is intended for use as a non-invasive post-processing software to evaluate calcified plaques in the coronary arteries, which present a risk for coronary artery disease. Imbio CAC Software uses machine learning to analyze non-contrast thoracic CT images and outputs a summary report containing Agatston score, arterial age, and calcified lesion mass and volume metrics of the calcification burden for the whole heart and individual coronary artery level. Additionally, Imbio CAC Software outputs annotated images previewing the segmentation of calcifications for informational purposes only. Imbio CAC Software is limited to the quantification of detected possible calcifications in adult patients $\geq$ 29 years of age. It does not diagnose coronary artery disease. The device output will be available to the users as part of the standard DICOM viewing workflow. The Imbio CAC Software results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CT images.

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.

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510(k) Summary

K230112

1.1 Submission Owner and Correspondent

Imbio, Inc.
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
Kai Ludwig, Senior Imaging Scientist.

1.2 Date Summary Prepared

January 13, 2023

1.3 Device Trade Name

CAC Software

1.4 Device Common Name

Automated computer-assisted coronary artery calcification segmentation and reporting software

1.5 Device Classification Name

Computed tomography x-ray system. Classified as Class 2 at 21 CFR 892.1750, product code JAK.

1.6 Legally Marketed Device To Which The Device Is Substantially Equivalent

The CAC Software is substantially equivalent to the Zebra Medical Vision HealthCCSng cleared under K210085.

1.7 Description of the Device

The Imbio CAC Software is a set of medical image post-processing computer algorithms that together performs automated coronary artery calcification segmentation and reports a total Agatston score, calcified lesion mass and volume, and arterial age from thoracic computed tomography (CT) images. The Agatston score, calcified lesion mass and volume are reported both as a total and for each of the following individual coronary arteries: right coronary artery (RCA), left anterior descending (LAD), left circumflex (LCx). The Imbio CAC 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 CAC Software is a Software and 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 CAC Software is an aid only used to support a physician in the analysis of CT images.

The Imbio CAC Software program reads in thoracic CT DICOM datasets, processes the data, then writes output DICOM files and summary reports to a specified directory. Imbio CAC Software outputs DICOMs of the original input DICOM CT images overlaid with color-codings representing the coronary artery calcification segmentations. Additionally, a summary PDF report is output.

Imbio CAC 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.

1.8 Indication for Use

Imbio CAC Software is intended for use as a non-invasive post-processing software to evaluate calcified plaques in the coronary arteries, which present a risk for coronary artery disease. Imbio CAC Software uses machine learning to analyze non-contrast thoracic CT images and outputs a summary report containing Agatston score, arterial age, and calcified lesion mass and volume metrics of the calcification burden for the whole heart and individual coronary artery level. Additionally, Imbio CAC Software outputs annotated images previewing the segmentation of calcifications for informational purposes only. Imbio CAC Software is limited to the quantification of detected possible calcifications in adult patients $\geq$ 29 years of age. It does not diagnose coronary artery disease. The device output will be available to the users as part of the standard DICOM viewing workflow. The Imbio CAC Software results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CT images.

1.9 Technological Characteristics

Table 1.1 compares the technological characteristics between the proposed CAC Software and the predicate Zebra Medical Vision HealthCCSng.

Table 1.1: Technological Characteristics Comparison with Predicate Device

Indications for Use	Due to the length of the statement, see below.	Due to the length of the statement, see below.	Different but does not introduce questions of safety and effectiveness.

Characteristic	Proposed Device CAC Software	Predicate Device Zebra Medical Vision HealthCCSng	Comparison
Regulatory			
FDA Clearance	TBD	K210085 (9/9/2021)	-
Product Code	JAK	JAK	Same
Class	II	II	Same
Regulation	21 CFR 892.1750	21 CFR 892.1750	Same
Software	Device is software only	Device is software only	Same
Level of Concern	Moderate	Moderate	Same
General			
Modality	CT	CT	Same
Anatomical Site	Thoracic, Chest, Cardiac	Thoracic, Chest, Cardiac	Same
Support Input CT Scan	Low and standard dose. Cardiac-gated and non-cardiac-gated. Up to 3mm slice thickness.	Low and standard dose. Non-cardiac-gated. Up to 3mm slice thickness.	Different - Predicate is not labeled for use in cardiac-gated scans.
Image Format	DICOM	DICOM	Same
Use Environment	Hospitals and Clinics including Inpatient and outpatient, and lung cancer screening programs.	Hospitals and Clinics including Inpatient and outpatient, and lung cancer screening programs.	Same
Quantification			
Calcium Detection	Automatic	Automatic	Same
Default Threshold	130 (HU)	130 (HU)	Same
Calcium Reporting	CAC score and reference 5 category CAC risk	3 category CAC risk	Different - Predicate does not report CAC score and combines lower risk categories.
Display and Outputs			
Outputs	DICOM Report and CAC annotated DICOM images.	DICOM Report and CAC annotated DICOM images.	Same
Alteration of original image	No	No	Same
Image Viewing	Images viewed on existing viewing workstation.	Images viewed on existing viewing workstation.	Same

Characteristic	**Proposed Device CAC Software**	**Predicate Device Zebra Medical Vision HealthCCSng**	**Comparison**
Communication with Patient	Does not communicate with patients.	Does not communicate with patients.	Same

Proposed Device CAC Software Indication for Use: Imbio CAC Software is intended for use as a non-invasive post-processing software to evaluate calcified plaques in the coronary arteries, which present a risk for coronary artery disease. Imbio CAC Software uses machine learning to analyze non-contrast thoracic CT images and outputs a summary report containing Agatston score, arterial age, and calcified lesion mass and volume metrics of the calcification burden for the whole heart and individual coronary artery level. Additionally, Imbio CAC Software outputs annotated images previewing the segmentation of calcifications for informational purposes only. Imbio CAC Software is limited to the quantification of detected possible calcifications in adult patients $\geq$ 29 years of age. It does not diagnose coronary artery disease. The device output will be available to the users as part of the standard DICOM viewing workflow. The Imbio CAC Software results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment of CT images.

Predicate Device Zebra Medical Vision HealthCCSng Indications for Use: HealthCCSng device is intended for use as a non-invasive post-processing software to evaluate calcified plaques in the coronary arteries, which present a risk for coronary artery disease. The software generates an estimated coronary artery calcium detection category. The HealthCCSng device analyzes existing non-cardiac-gated CT studies that include the heart of adult patients above the age of 30. The device generates a three-category output representing the estimated quantity of calcium detected together with the preview axial images of the detected calcium meant for informational purposes only. The device output will be available to the radiologist as part of their standard workflow. The HealthCCSng results are not intended to be used on a stand-alone basis for risk attribution, clinical decision-making or otherwise preclude clinical assessment of CT studies.

1.10 Clinical Study

Non-clinical testing was conducted in the form of a retrospective, multi-center, standalone device performance assessment. 500 anonymized chest CT series meeting the input requirements for Imbio CAC Software were curated from a variety of sources including large publically available databases and private imaging data brokers. Exclusion criteria included:

- CTs from pediatric patients ($<$ 22 years old)
- Contrast-enhanced acquisitions
- Scans with significant respiratory motion
- Scans with severe metal artifacts
- Scans containing non-thoracic anatomy

The mean age of patients whose scans were included in the performance assessment was 64.3 years with a standard deviation of 10 years with the oldest and youngest patient being 90+ (not listed above 90 years old) and 29 years old, respectively. Gender distrubution was 41.7% male and 42.5 % female with 15.6% of the data having no gender information. Images originated from GE Medical Systems (65.1%), Siemens (19.4%), Imatron (15.2%), and Philips (0.2%) scanners. There was an equal split of ECG-gated and non-gated acquisitions.

All chest CT series were annotated by experienced 3D Image Post-Processing Technologists using an FDA-cleared semi-automated CAC scoring software program. These images and the corresponding CAC scores were used as ground truth for Imbio CAC Software validation.

The primary endpoint was to evaluate the cardiovaclar disease risk category across all cases between Imbio CAC Software and the ground truth. For a 5-category risk assessment, the Cohen's kappa between Imbio CAC Software and the ground truth was 0.907 (95% CI 0.895, 0.920), which met the acceptance criteria of kappa > 0.859.

1.11 Biocompatibility

Biocompatibility testing is not applicable for the CAC Software.

1.12 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.