September 27, 2024

BunkerHill Health
% Nitya Narayanan
Director of Regulatory Affairs
436 Bryant Street
SAN FRANCISCO, CA 94107

Re: K240369
Trade/Device Name: CAC (gated) Algorithm
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: August 23, 2024
Received: August 26, 2024

Dear Nitya Narayanan:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240369

Device Name

CAC (gated) Algorithm

Indications for Use *(Describe)*

CAC (gated) is a software device intended for use in estimating presence and quantity of coronary artery calcium for patients aged 30 years and above. The device automatically analyzes non-contrast electrocardiogram (ECG) gated cardiac computed tomography (CT) images collected and outputs the segmentation (intended for informational purposes only) and quantification of detected calcium.

The output of the subject device is made available to the physician on-demand as part of his or her standard workflow. The device-generated quantification can be viewed in the patient report at the discretion of the physician, and the physician also has the option of viewing the device-generated calcium segmentation in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original cardiac CT scan; both are still available to be viewed and used at the discretion of the physician.

The device is intended to provide information to the physician to provide assistance during review of the patient's case. Results of the subject device are not intended to be used on a stand-alone basis and are solely intended to aid and provide information to the physician. In all cases, further action taken on a patient should only come at the recommendation of the physician after further reviewing the patient's results.

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

BunkerHill Health Inc.'s CAC (gated) Device

BunkerHill Health Inc.

436 Bryant Street

San Francisco CA 94107

Phone: (650) 842-0198
Contact Person: Nishith Khandwala

Date Prepared: September 18, 2024

Proposed Device

Proprietary Name	CAC (gated) Device
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	JAK
Regulatory Class	II

Predicate Device(s)

Proprietary Name	Imbio's CAC Software
Premarket Notification	K230112
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	JAK
Regulatory Class	II

Proprietary Name	iCAC Device
Premarket Notification	K230223
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	JAK
Regulatory Class	II

Device Description

Bunkerhill CAC (gated) is a software as a medical device (SaMD) product that interfaces with compatible and commercially available CT systems. Bunkerhill CAC (gated) localizes, quantifies,

and categorizes coronary artery calcification in non-contrast, electrocardiogram (ECG) gated, chest CT studies. The core features of the product are:

- Categorization of the coronary artery calcium burden in the form of a range of Agatston scores. Calcium score groupings are defined as one of the four following ranges of Agatston units:
    a. Group 1: 0 Agatston units
    b. Group 2: 1-99 Agatston units
    c. Group 3: 100-399 Agatston units
    d. Group 4: 400+ Agatston units
- Quantification of the overall coronary artery calcium burden in the form of an exact Agatston Score.
- Quantification of each coronary artery's (left main (LCA), left anterior descending (LAD), left circumflex (LCX), and right coronary artery (RCA)) calcium burden in the form of an exact Agatston score.
- Localization of estimated calcium burden in the form of a CAC segmentation applied to a copy of the original CT scan (intended for informational purposes only).

Intended Use / Indications for Use

CAC (gated) is a software device intended for use in estimating presence and quantity of coronary artery calcium for patients aged 30 years and above. The device automatically analyzes non-contrast electrocardiogram (ECG) gated chest computed tomography (CT) images collected and outputs the segmentation (intended for informational purposes only) and quantification of detected calcium.

The output of the subject device is made available to the physician on-demand as part of his or her standard workflow. The device-generated quantification can be viewed in the patient report at the discretion of the physician, and the physician also has the option of viewing the device-generated calcium segmentation in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original ECG-gated cardiac CT scan; both are still available to be viewed and used at the discretion of the physician.

The device is intended to provide information to the physician to provide assistance during review of the patient's case. Results of the subject device are not intended to be used on a stand-alone basis and are solely intended to aid and provide information to the physician. In all cases, further action taken on a patient should only come at the recommendation of the physician after further reviewing the patient's results.

Summary of Technological Characteristics

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both the predicate and the subject device use deep-learning algorithms to identify the presence of coronary artery calcium deposits and quantify calcium burden in adult patients.
- Both devices analyze computed tomography (CT) images that are sent to the software in DICOM format.
- Both the predicate and the subject device quantify the calcium burden of the coronary arteries.

- Both devices serve as support tools to provide information to the physician. However, they do not replace clinical evaluation and do not alter the standard of care.
- Both devices segment the calcium area on an image and generate a report.

A table comparing the key features of the subject and predicate devices is provided below.

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE

Characteristic	**Subject Device -CAC (gated) algorithm**	**Primary Predicate Device: Imbio Inc's CAC SW (K230112)**	**Secondary Predicate Device: iCAC (K230223)**	**Summary**
Intended Use / Indications for Use	CAC (gated) is a software device intended for use in estimating presence and quantity of coronary artery calcium for patients aged 30 years and above. The device automatically analyzes non-contrast electrocardiogram (ECG) gated chest computed tomography (CT) images collected and outputs the segmentation (intended for informational purposes only) and quantification of detected calcium. The output of the subject device is made available to the physician on-demand as part of his or her standard workflow. The device-generated quantification can be viewed in the patient report at the discretion of the physician, and the physician also has the option of viewing the device-generated calcium segmentation in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original ECG-gated cardiac CT scan; both are still available to be viewed and	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 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 ≥ 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	iCAC is a software device intended for use in estimating presence and quantity of coronary artery calcium for patients aged 30 years and above during routine care. The device automatically analyzes non-gated, chest computed tomography (CT) images collected during routine care and outputs a visual representation of estimated coronary artery calcium segmentation (intended for informational purposes only) and both exact and four-category quantitative estimates of the patient's coronary artery calcium burden in Agatston units. The output of the subject device is made available to the physician on-demand as part of his or her standard workflow. The device-generated calcium score or score group can be viewed in the patient report at the discretion of the physician, and the physician also has the option of viewing the device-generated calcium segmentation in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original	Same: Both primary and secondary predicates are non-invasive post-processing SW to evaluate calcified plaque in coronary arteries. Both use CT images. Similar to primary predicate device, CAC (gated) outputs a summary report containing Agatston score, i.e. the calcification burden for the whole heart and at individual coronary artery level. Annotated images previewing the segmentation of calcifications is provided for information purposes. Both subject and predicates are not intended to be used on a stand-alone basis.

Characteristic	Subject Device -CAC (gated) algorithm	Primary Predicate Device: Imbio Inc's CAC SW (K230112)	Secondary Predicate Device: iCAC (K230223)	Summary
	used at the discretion of the physician. The device is intended to provide information to the physician to provide assistance during review of the patient's case. Results of the subject device are not intended to be used on a stand-alone basis and are solely intended to aid and provide information to the physician. In all cases, further action taken on a patient should only come at the recommendation of the physician after further reviewing the patient's results.	clinical decision-making or otherwise preclude clinical assessment of CT images.	ECG-gated cardiac CT scan; both are still available to be viewed and used at the discretion of the physician. The device is intended to provide information to the physician to provide assistance during review of the patient's case. Results of the subject device are not intended to be used on a stand-alone basis and are solely intended to aid and provide information to the physician. In all cases, further action taken on a patient should only come at the recommendation of the physician after further reviewing the patient's results.	
Type of Interpretation	Adjunctive information	Adjunctive information	Adjunctive information	Same
Intended User	Interpreting physicians	Interpreting physicians	Interpreting physicians	Same
Patient population	Patients aged 30 years and above	Patients above the age of 29	Patients aged 30 years and above	Same
Anatomical location	Cardiac	Thoracic, Chest, cardiac	Chest	Same
Intended location	Medical facility	Medical facility	Medical facility	Same
Rx or OTC	Rx	Rx	Rx	Same
Measurement scale	Agatston units	Agatston units	Agatston units	Same
Product code	JAK	JAK	JAK	Same
Regulation number	21 CFR §892.1750	21 CFR §892.1750	21 CFR §892.1750	Same
Modality	Computed tomography (CT)	Computed tomography (CT)	Computed tomography (CT)	Same
Image format	DICOM	DICOM	DICOM	Same
Supported CT scan	Cardiac gated CT scan	Non-cardiac-gated and cardiac gated CT scan	Non-cardiac-gated CT scan	Similar. Primary predicate is for both gated and non-gated scans, therefore

Characteristic	Subject Device -CAC (gated) algorithm	Primary Predicate Device: Imbio Inc's CAC SW (K230112)	Secondary Predicate Device: iCAC (K230223)	Summary
				subject device which works on gated scans is a subset. Note: Secondary predicate iCAC clearance (K230223) works on non-gated scans.
Slice thickness	Up to 3mm	Up to 3mm	Up to 5mm	Same
Calcification detection	Automatic	Automatic	Automatic	Same
Default threshold of calcium	130 HU (Hounsfield Units)	130 HU (Hounsfield Units)	130 HU (Hounsfield Units)	Same
Coronary artery calcification quantification method	CAC detection category (based on Agatston score), exact Agatston score including vessel specific Agatston scores.	CAC detection category (based on Agatston score), including vessel specific Agatston scores	CAC detection category (based on Agatston score), exact Agatston score	Same
Main image quality	DICOM	DICOM	DICOM	Same
Annotation of detected calcium	Yes	Yes	Yes	Same
Generate patient report	Optional to copy result to clipboard, insert in report, DICOM Secondary Capture	Optional to copy result to clipboard, insert in report, DICOM Secondary Capture	Optional to copy result to clipboard, insert in report, DICOM Secondary Capture	Same
Report of the calcium score	Yes, Coronary Calcium Detection Category and exact Agatston score. 4 categories (for detection category): • 0 • 1-99 • 100-399 • ≥400	Yes, Coronary Calcium Detection Category 5 categories	Yes, Coronary Calcium Detection Category and exact Agatston score. 4 categories (for detection category): • 0 • 1-99 • 100-399 • ≥400	Similar, CAC (gated) provides 4-category estimates whereas primary predicate provides 5 categories. Currently cleared iCAC (secondary predicate) has 4-categories similar to the subject device.

Figure 1: SE Table

Performance Data

Safety and performance of the CAC (gated) Device has been evaluated and verified in accordance with software specifications and applicable performance standards through Software Development and Validation & Verification Process to ensure performance according to specifications, User Requirements and Federal Regulations and Guidance documents, “Content of Premarket Submissions for Device Software Functions”-June 2023.

The CAC (gated) Device performance was validated in a stand-alone retrospective study for overall agreement of the device output compared to the established ground truth. The pivotal testing dataset consisted of gated CT studies from six (6) geographically diverse sites. The sample included adequate representation from each coronary calcium detection category. The CAC (gated) Device’s overall agreement was determined by comparing the device output coronary calcium detection category to the ground truth coronary calcium detection category.

The primary endpoint was to evaluate the cardiovascular disease risk category across all cases between the subject device and the ground truth. Primary acceptance criteria for the pivotal testing study was defined as Cohen’s weighted kappa for the 4-category score group assessment of at least 0.90. The BunkerHill device demonstrated a Cohen’s weighted kappa of 0.972 (95%CI 0.958, 0.987) thus exceeding the primary acceptance criteria for the pivotal testing study.

Conclusions

The CAC (gated) Device is as safe and effective as the predicate devices (Imbio’s CAC Software K230112 and iCAC device K230223). The CAC (gated) Device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the CAC (gated) Device and its predicate devices raise no new issues of safety or effectiveness.