January 27, 2025

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

Re: K243229
Trade/Device Name: Bunkerhill AVC
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: December 18, 2024
Received: December 23, 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
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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)*

K243229

Device Name

Bunkerhill AVC

Indications for Use *(Describe)*

Bunkerhill AVC is a software device intended for use in detecting presence and estimating quantity of aortic valve calcification for adult patients aged 40 years and above. The device automatically analyzes non-gated, non-contrast chest computed tomography (CT) images collected during clinical care and outputs the region of interest (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 region of interest in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original non-gated, non-contrast 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.

510(K) SUMMARY

Bunkerhilll AVC

BunkerHill Health Inc.
436 Bryant Street
San Francisco CA 94107

Phone: (408) 8028146
Contact Person: Nitya Narayanan

Date Prepared: January 27, 2025

Proposed Device

Proprietary Name	Bunkerhill AVC
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	JAK
Regulatory Class	II

Predicate Device

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 AVC is a software as a medical device (SaMD) product that interfaces with compatible and commercially available computed tomography (CT) systems. Bunkerhill AVC detects, localizes, and quantifies aortic valve calcification in non-gated, non-contrast chest CT studies. The core features of the product are:

- **Detection** of aortic valve calcification at an Agatston-equivalent score threshold of 0 AU.
- **Estimation** of the overall aortic valve calcification burden in the form of an estimated Agatston-equivalent Score.
- **Localization** of estimated calcium burden in the form of AVC region of interest applied to a copy of the original CT scan.

Intended Use / Indications for Use

Bunkerhill AVC is a software device intended for use in detecting presence and estimating quantity of aortic valve calcification for adult patients aged 40 years and above. The device automatically analyzes non-gated, non-contrast chest computed tomography (CT) images collected during clinical care and outputs the region of interest (*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 region of interest in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original non-gated, non-contrast 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.

Note: The only difference in intended use between subject and predicate device is that while predicate device is used in coronary artery calcification, subject device is used to estimate calcification in aortic valve. The differences in anatomical area do not raise any new questions of safety and effectiveness. Both devices assist the medical professionals in detecting presence and location of calcifications. Both subject and predicate devices are to aid medical professionals in viewing and analyzing cardiac computed tomography (CT) data to determine presence and extent of calcification.

A table comparing the intended use of the subject and predicate devices is provided below.

	Proposed Device: Bunkerhill AVC	Predicate Device: iCAC Device (K230223)
Intended use / Indications for use	Bunkerhill AVC is a software device intended for use in detecting presence and estimating quantity of aortic valve calcification for adult patients aged 40 years and above. The device automatically analyzes non-gated, non-contrast chest computed tomography (CT) images collected during clinical care and outputs the region of interest (*intended for informational purposes only*) and quantification of detected calcium.	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, non-contrast 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.

	Proposed Device: Bunkerhill AVC	Predicate Device: iCAC Device (K230223)
	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 region of interest in a diagnostic image viewer. The subject device output in no way replaces the original patient report or the original non-gated, non-contrast 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.	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 chest 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

- Both the predicate and the subject device use deep-learning algorithms to identify the presence of calcification and estimate calcification.
- Both devices analyze non-gated chest computed tomography (CT) images that are sent to the software in DICOM format.
- Both the predicate and the subject device quantify the calcification by generating a metric (an estimated score). These metrics are both based on the Agatston-equivalent score.
- Both devices serve as support tools to provide information to the physician. Both can be used on-demand or optionally by the physician and do not provide a definitive diagnosis. Both devices do not replace clinical evaluation and do not alter the standard of care. Both require the physician to use this information to decide next steps and/or additional diagnostic work up.
- Both devices provide a visual representation of the region of the detected calcification for better explainability and for the physician to confirm the device output.

The following technological difference exists between the subject and predicate devices:

- The predicate device estimates presence and quantity of coronary artery calcium and additionally defines 4 detection categories for reporting the coronary artery calcium score whereas the subject device only provides a binary output (presence/absence of calcification) and an estimated Agatston-equivalent score for aortic valve calcium. The predicate device provides a segmentation output, whereas the subject device provides a circular region of interest (ROI) around detected calcification.

	Proposed Device: Bunkerhill AVC	**Predicate Device:** iCAC Device (K230223)	**Summary**
Product code	JAK	JAK	Same
Regulation number	21 CFR §892.1750	21 CFR §892.1750	Same
Modality	Computed tomography (CT)	Computed tomography (CT)	Same
Image format	DICOM	DICOM	Same
Contrast	Non-contrast	Non-contrast	Same
Supported CT scan	Non-cardiac-gated CT scan	Non-cardiac-gated CT scan	Same
Slice thickness	Up to 5 mm	Up to 5 mm	Same
Calcification detection	Automatic	Automatic	Same
Main image quality	DICOM	DICOM	Same
Annotation of detected calcium	Yes	Yes	Same
Visual Output format	Visual output in the form a Circular Region of Interest (ROI) around detected calcification (intended for informational purposes only). The estimated visual output can be viewed by the physician in a	Outputs a visual representation of estimated coronary artery calcium segmentation (intended for informational purposes only). The	Predicate device shows estimated segmentation as one of the device outputs whereas subject device shows a ROI, not segmentation.

	diagnostic image viewer. The physician's standard method for viewing unaltered chest CT scans in PACS will remain available to them even if the subject device is being used. However, the physician will also have an option to view the visual output estimated by the subject device as a separate series within PACS.	estimated calcium segmentation can be viewed by the physician in a diagnostic image viewer. The physician's standard method for viewing unaltered chest CT scans in PACS will remain available to them even if the subject device is being used. However, the physician will also have an option to view the calcium segmentation estimated by the subject device as a separate series within PACS.	Both are for information only.
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	Same

Report of the calcium score	Yes, estimated Agatston-equivalent score and binary output (presence/absence)	Yes, Coronary Calcium Detection Category and estimated Agatston score 4 detection categories	iCAC provides estimation of coronary calcium burden whereas subject device provides estimation of calcification on aortic valve.
Type of Interpretation	Adjunctive information	Adjunctive information	Same
Intended User	Qualified medical professionals such as cardiologists or radiologists	Interpreting physicians	Similar
Patient population	Patients aged 40 years and above	Patients above the age of 30	Similar
Anatomical location	Chest	Chest	Same
Intended location	Medical facility	Medical facility	Same
Rx or OTC	Rx	Rx	Same
Measurement scale	Agatston-equivalent units	Agatston-equivalent units	Same

Performance Data

Safety and performance of Bunkerhill AVC 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".

The Bunkerhill AVC performance was validated in a stand-alone retrospective study for localization and agreement of the device output compared to the established ground truth. The pivotal dataset was curated from thirty-three (33) sites across three geographical regions in the United States. The primary endpoint was a Bland Altman agreement analysis and the secondary endpoint was Precision and Recall of the circular ROI. The acceptance criteria were derived from the performance of the predicate device and clinical literature in high impact journals that investigate the inter-reader agreement of manual segmentation.

The observed bias in the pivotal study was –5.15 AU and lower and upper limits agreements were –200.96 AU and 190.65 AU, respectively. As result, Bunkerhill AVC met the mean difference and limits of agreement acceptance criteria, thus satisfying the endpoints of the pivotal testing study. The low mean difference demonstrates that Bunkerhill AVC has a bias of low magnitude. The observed Precision was 0.826 (0.784, 0.863) and the observed Recall was 0.855 (0.818, 0.890). As a result, Bunkerhill AVC met the secondary endpoint acceptance criteria.

The testing demonstrates that the device is substantially equivalent to the predicate as required by 21 CFR 807.92(b)(3) since both the predicate and subject device demonstrated that with the cited mean difference and limits of agreement, the primary endpoint for calcium score was met.

Conclusions

Bunkerhill AVC is substantially equivalent to the predicate iCAC Device (K230223). The subject 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 summary, any minor differences between Bunkerhill AVC and the iCAC Device do not raise any issues of safety or effectiveness.