March 6, 2026

BunkerHill Health
% John Smith, Partner
Hogan Lovells US LLP
555 Thirteenth St., NW
WASHINGTON DC 20004

Re: K260166
Trade/Device Name: Bunkerhill Contrast CAC
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: January 20, 2026
Received: January 20, 2026

Dear John Smith:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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 Radiological 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.

510(k) Number *(if known)*
K260166

Device Name
Bunkerhill Contrast CAC

Indications for Use *(Describe)*
Bunkerhill Contrast CAC is a software device intended for use in detecting presence and estimating quantity of coronary artery calcification for adult patients aged 30 years and above. The device automatically analyzes non-gated, contrast-enhanced 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, contrast-enhanced 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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K260166

510(K) SUMMARY
Bunkerhilll Contrast CAC

BunkerHill Health
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555 Thirteenth St., NW
Washington, District of Columbia 20004

Phone: (202) 637 3638
Contact Person: John Smith
Date Prepared: February 23, 2026

Proposed Device

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

Primary 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

Reference Device

Proprietary Name	Bunkerhill AVC
Premarket Notification	K243229
Classification Name	Computed tomography x-ray system
Regulation Number	21 CFR 892.1750
Product Code	JAK
Regulatory Class	II

Device Description

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

- Detection of coronary artery calcification volume at a threshold of 0 mm3.
- Quantification of the overall coronary artery calcification burden in the form of an estimated volume score.
- Localization of estimated calcium burden in the form of a CAC region of interest applied to a copy of the original CT scan.

Intended Use / Indications for Use

Bunkerhill Contrast CAC is a software device intended for use in detecting presence and estimating quantity of coronary artery calcification for adult patients aged 30 years and above. The device automatically analyzes non-gated, contrast-enhanced 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, contrast-enhanced 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.

Technological Characteristics Comparison:

The subject device, predicate device, and reference device are all intended for use in detecting presence and estimating quantity calcification. The only difference in intended use between subject and predicate device is that while the predicate device analyzes non-gated, non-contrast chest CT images the subject device analyzes non-gated, contrast-enhanced chest CT images. Given the identical principles of operation and technological characteristics, the differences do not raise any new questions of safety and effectiveness. Both the subject and predicate device 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.

Table 1: Substantial Equivalence-Intended Use Table

	Proposed Device: Bunkerhill Contrast CAC	**Predicate Device: Bunkerhill iCAC Device (K230223)**	**Reference: Device: Bunkerhill AVC (K243229)**
Intended use / Indications for use	Bunkerhill Contrast CAC is a software device intended for use in detecting presence and estimating quantity of coronary artery calcification for adult patients aged 30 years and above. The device automatically analyzes non-gated, contrast-enhanced 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, contrast-enhanced CT scan; both are still	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. 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	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.

	Proposed Device: Bunkerhill Contrast CAC	Predicate Device: Bunkerhill iCAC Device (K230223)	Reference: Device: Bunkerhill AVC (K243229)
	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.	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.	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(s) 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).
- 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.

- There are no major technological differences between the subject device and predicate device. The following technological difference exists between the subject and predicate devices:

    - The subject device outputs volume in mm3 using a deterministic mathematical formula based on the raw segmentation maps, while the predicate devices output Agatstons Units using a deterministic formula based on raw segmentation maps.

    - The information-only device output is that while the predicate device displays estimated calcium segmentation, the subject device shows a visual output in the form of a Region of Interest (ROI). The rationale behind this was to ensure that the interpreting physician is able to visualize the underlying calcification. The user has the option to delete the visual outputs if they do not agree with the results in both the subject and predicate device.

    - The subject device does not have a categorical output as coronary artery calcification. This aspect of the subject device is most similar to the reference device.

	Proposed Device: Bunkerhill Contrast CAC	**Predicate Device:** iCAC (K230223)	**Reference Device:** Bunkerhill AVC (K243229)	**Summary** *(compared to predicate)*
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	Contrast-enhanced, Non-cardiac-gated CT scan	Non-contrast, Non-cardiac-gated CT scan	Non-contrast, Non-cardiac-gated CT scan	Similar
Slice thickness	Up to 5 mm	Up to 5 mm	Up to 5 mm	Same
Calcification detection	Automatic	Automatic	Automatic	Same
Main image quality	DICOM	DICOM	DICOM	Same
Annotation of detected calcium	Yes	Yes	Yes	Same
Visual Output format	Visual output in the form a Region of Interest or ROI (intended for informational purposes only). The estimated visual output can	Outputs a visual representation of estimated coronary artery calcium segmentation (intended	Visual output in the form a Region of Interest or ROI (intended for informational purposes	Similar

	Proposed Device: Bunkerhill Contrast CAC	**Predicate Device:** iCAC (K230223)	**Reference Device:** Bunkerhill AVC (K243229)	**Summary** *(compared to predicate)*
	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 visual output estimated by the subject device as a separate series within PACS.	for informational purposes only). The 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.	only). The estimated visual output 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 visual output estimated by the subject device as a separate series within PACS.	
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, estimated calcification volume (mm^3) score and binary output (presence/absence)	Yes, Coronary Calcium Detection Category and exact Agatston score 4 detection categories	Yes, estimated exact Agatston-equivalent score and binary output (presence/absence)	Similar
Type of Interpretation	Adjunctive information	Adjunctive information	Adjunctive information	Same
Intended User	Qualified medical professionals such as	Interpreting physicians	Qualified medical professionals such as	Same
Patient population	Patients aged 30 years and above	Patients above the age of 30	Patients above the age of 40	Same
Anatomical location	Chest (Coronary Artery)	Chest (coronary artery)	Chest (aortic valve)	Same
Intended location	Medical facility	Medical facility	Medical facility	Same
Rx or OTC	Rx	Rx	Rx	Same

Performance Data

Safety and performance of Bunkerhill Contrast CAC 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" and Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

The Contrast CAC performance was validated in a stand-alone retrospective study for detection, localization and agreement of the device output compared to the established ground truth. The pivotal dataset was curated from multiple sites across three geographical regions in the United States. The co-primary endpoints of Sensitivity and Specificity (Se/Sp), Precision and Recall of the circular ROI and correlation coefficient were met successfully. 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 co-primary endpoint of a Bland Altman agreement was also successfully met. The observed bias in the pivotal study was 25.41 mm3 and lower and upper limits agreements were –249.13 mm3 and 198.32 mm3, respectively. As result, Bunkerhill Contrast CAC met the mean difference and limits of agreement acceptance criteria, thus satisfying all the endpoints of the pivotal testing study. The low mean difference demonstrates that Bunkerhill Contrast CAC has a bias of low magnitude. The observed Sensitivity 0.957 (0.924, 0.991), the observed Specificity was 0.929 (0.882, 0.976), the observed Precision was 0.814 (0.776, 0.850) and the observed Recall was 0.755 (0.712, 0.797). As a result, Bunkerhill Contrast CAC met all study acceptance criteria.

An additional bridging study comparing the volume generated by the Contrast CAC device on a contrast-enhanced image to the calcification volume on the same patient calculated on a non-contrast image was conducted. This study intended to further demonstrate the validity of the Contrast CAC device in detecting and quantifying coronary artery calcification in patients in line with its intended use. 50 cases were included in the bridging study. The study met the predefined acceptance criteria with a mean bias of -4.36 mm3 and LOA of -76.63 mm3 to 67.91 mm3.

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 Contrast CAC is substantially equivalent to the predicate iCAC Device (K230223) and reference Bunkerhill AVC (K243229). The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. 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 Contrast CAC and the predicate devices do not raise any issues of safety or effectiveness.