



April 8, 2025

BunkerHill Health
% Eren Alkan
Director of AI Algorithms
436 Bryant Street
SAN FRANCISCO, CA 94107

Re: K242295
Trade/Device Name: BunkerHill BMD
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: Class II
Product Code: KGI
Dated: March 10, 2025
Received: March 11, 2025

Dear Eren Alkan:

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,

A large, light blue watermark of the letters "FDA" is visible in the background. Overlaid on this watermark is the name "Lu Jiang" written in a black, cursive script.

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

Indications for Use

Submission Number (if known)

K242295

Device Name

Bunkerhill BMD

Indications for Use (Describe)

The Bunkerhill BMD Algorithm is a post-processing AI-powered software intended for adults 30 years and above to assess estimated DXA-measured average areal bone mineral density of spinal bones from existing CT scans and outputs a flag for low bone density below a pre-specified threshold. It is not intended to replace DXA or any other tests dedicated to BMD measurement.

Bunkerhill BMD is an opportunistic AI-powered tool that enables:(1) retrospective assessment of bone density from CT scans acquired for other purposes, (2) assessment of bone density in conjunction with another medically appropriate procedure involving CT scans, and (3) assessment of bone density without a phantom as an independent measurement procedure

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
[BUNKERHILL BMD]

K242295

Bunkerhill, Inc.
436 Bryant Street
San Francisco CA 94107
Ph: 650-8420198
Prepared By: Eren Alkan
Date Prepared: April 3, 2025

Proposed Device

Proprietary Name	Bunkerhill BMD
Classification Name	Bone Densitometer
Regulation Number	21 CFR 892.1170
Product Code	KGI
Regulatory Class	II

Predicate Device

Proprietary Name	ABMD software
Premarket Notification	K213760
Classification Name	Bone Densitometer
Regulation Number	21 CFR 892.1170
Product Code	KGI
Regulatory Class	II

Device Description

The Bunkerhill BMD application is a software only medical device (SaMD) that includes deep-learning-based computer vision and post-processing algorithms that estimates the bone mineral density from previously obtained computed tomography (CT) images.

The results from Bunkerhill BMD are not intended to be used as the primary input for clinical decision making, but rather are intended to provide information that may assist the clinician to identify 'findings of interest' within existing imaging studies.

Intended Use / Indications for Use

The Bunkerhill BMD Algorithm is a post-processing AI-powered software intended for adults 30 years and above to assess estimated DXA-measured average areal bone mineral density of spinal bones from existing CT scans and outputs a flag for low bone density below a pre- specified threshold. It is not intended to replace DXA or any other tests dedicated to BMD measurement.

Bunkerhill BMD is an opportunistic AI-powered tool that enables:(1) retrospective assessment of bone density from CT scans acquired for other purposes, (2) assessment of bone density in conjunction with another medically appropriate procedure involving CT scans, and (3) assessment of bone density without a phantom as an independent measurement procedure

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 estimate the average bone mineral density in spinal bones.
- Both devices analyze computed tomography (CT) images that are sent to the software in DICOM format.
- 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 provide and generate a report.

There are no technological differences between the subject and predicate device.

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

	Proposed Device: Bunkerhill BMD	Predicate Device: ABMD SW(K213760)	Summary
Product code	KGI	KGI	Same
Regulation number	21 CFR §892.1170	21 CFR §892.1170	Same
Modality	Computed tomography (CT)	Computed tomography (CT)	Same
Image format	DICOM	DICOM	Same

Device provides estimates of bone mineral density, T- scores and Z- scores	Yes	Yes	Similar, subject device provides a subset of predicate device outputs i.e. only T- score group.
User	Healthcare provider	Healthcare Provider	Same

	Proposed Device: Bunkerhill BMD	Predicate Device: ABMD SW(K213760)	Summary
Retrospective measurements from CT scans	CT scan images can be selected and inputted to the software	CT scan images can be selected and inputted to the software.	Same
Automatic averaging Hounsfield Units	Software automatically measures and averages Hounsfield units in the regions of interest of spinal bones.	Software automatically measures and averages Hounsfield units in the trabecular region of the spinal bones.	Same
Main image quality	DICOM	DICOM	Same
Calibration	Software outputs calibrated BMD score.	Software outputs calibrated BMD score.	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	Same

Performance Data

Safety and performance of the Bunkerhill BMD 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, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.

Bunkerhill BMD 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 371 CT studies from four (4) geographically diverse sites. The Bunkerhill BMD algorithm achieved a sensitivity of 81.0 (74.0 - 86.8) and specificity of 78.4 (72.3 - 83.7), which passed the acceptance criteria for the primary endpoint with lower bound 95% confidence interval of both Sensitivity and Specificity being greater than 70%. Additionally, the device achieved was evaluated across multiple secondary metrics, including a Pearson correlation coefficient of 0.791 (95% CI: 0.752–0.830), AUROC of 0.883 (95% CI: 0.849–0.916), PPV of 73.6% (95% CI: 66.4%–79.9%), and NPV of 84.8% (95% CI: 79.0%–89.5%), further supporting the robustness and reliability of the algorithm. Generalizability of the device performance was evaluated through subgroup analyses across key variables including patient age, sex, CT manufacturer, slice thickness, reconstruction kernel, and data collection site. The device demonstrated consistent sensitivity and specificity across all subgroups, with no statistically significant performance differences observed. These results support the generalizability of the device across the intended use population.

Conclusions

Bunkerhill BMD is as safe and effective as the predicate ABMD device (K213760). The BMD 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 BMD Device and its predicate devices raise no new issues of safety or effectiveness.