



December 19, 2025

HeartLung Corporation
Mark Scott
Official Applicant
2450 Holcombe Blvd
Houston, Texas 77021

Re: K252029

Trade/Device Name: AI-CVD®
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, KGI
Dated: November 24, 2025
Received: November 24, 2025

Dear Mark Scott:

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,



Jessica Lamb, Ph.D.
Assistant Director, Imaging Software 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

510(k) Number (if known)
K252029

Device Name
AI-CVD®

Indications for Use (Describe)

AI-CVD® is an opportunistic AI-powered quantitative imaging tool that provides automated CT-derived anatomical and density-based measurements for clinician review. The device does not provide diagnostic interpretation or risk prediction. It is solely intended to aid physicians and other healthcare providers in determining whether additional diagnostic tests are appropriate for implementing preventive healthcare plans. AI-CVD® has a modular structure where each module is intended to report quantitative imaging measurements for each specific component of the CT scan. AI-CVD® quantitative imaging measurement modules include coronary artery calcium (CAC) score, aortic wall calcium score, aortic valve calcium score, mitral valve calcium score, cardiac chambers volumetry, epicardial fat volumetry, aorta and pulmonary artery sizing, lung density, liver density, bone mineral density, and muscle & fat composition.

Using AI-CVD® quantitative imaging measurements and their clinical evaluation, healthcare providers can investigate patients who are unaware of their risk of coronary heart disease, heart failure, atrial fibrillation, stroke, osteoporosis, liver steatosis, diabetes, and other adverse health conditions that may warrant additional risk assessment, monitoring or follow-up. AI-CVD® quantitative imaging measurements are to be reviewed by radiologists or other medical professionals and should only be used by healthcare providers in conjunction with clinical evaluation.

AI-CVD® is not intended to rule out the risk of cardiovascular diseases. AI-CVD® opportunistic screening software can be applied to non-contrast thoracic CT scans such as those obtained for CAC scans, lung cancer screening scans, and other chest diagnostic CT scans. Similarly, AI-CVD® opportunistic screening software can be applied to contrast-enhanced CT scans such as coronary CT angiography (CCTA) and CT pulmonary angiography (CTPA) scans. AI-CVD® opportunistic bone density module and liver density module can be applied to CT scans of the abdomen and pelvis. All volumetric quantitative imaging measurements from the AI-CVD® opportunistic screening software are adjusted by body surface area (BSA) and reported both in cubic centimeter volume (cc) and percentiles by gender reference data from people who participated in the Multi-Ethnic Study of Atherosclerosis (MESA) and Framingham Heart Study (FHS). Except for coronary artery calcium scoring, other AI-CVD® modules should not be ordered as a standalone CT scan but instead should be used as an opportunistic add-on to existing and new CT scans.

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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K252029
510(K) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92:

1. Submitter

HeartLung Corporation
2450 Holcombe Blvd, Houston, TX 77021
Tel: (650) 448-8089
Contact: Dr. Morteza Naghavi
Date Prepared: Monday, June 9, 2025

2. Device

Subject Device: AI-CVD®
Trade Name: AI-CVD®
Common Name: AI-CVD®
Classification: Class II, 21 CFR 892.2050

Product Code: QIH, KGI

3. Predicate Device

Manufacturer: HeartLung Corporation
Trade Name: AutoChamber®
Reference 510(k): K240786

4. Reference Device

Manufacturer: HeartLung Corporation
Trade Name: ABMD Software
Predicate 510(k): K213760

5. Device Description

General Description

AI-CVD® is an opportunistic AI-powered modular tool that provides automated quantitative imaging reports on CT scans and outputs the following measurements:

- Coronary Artery Calcium Score
- Aortic Wall and Valves Calcium Scores
- Mitral Valve Calcium Score
- Cardiac Chambers Volume
- Epicardial Fat Volume
- Aorta and Main Pulmonary Artery Volume and Diameters
- Liver Attenuation Index



- Lung Attenuation Index
- Muscle and Visceral Fat
- Bone Mineral Density

The above quantitative imaging measurements enable care providers to take necessary actions to prevent adverse health outcomes.

Intended Patient Population

Patients who underwent a CT scan of chest or abdomen.

Principles of Ops

AI-CVD® modules are installed by trained personnel only. AI-CVD® is executed via parent software which provides the necessary inputs and receives the outputs. The software itself does not offer user controls or access.

AI-CVD® reads a CT scan (in DICOM format) and extracts scan specific information like acquisition time, pixel size, scanner type, etc. AI-CVD® uses trained AI models that automatically segment and report quantitative imaging measurements specific to each AI-CVD® module. The output of each AI-CVD® module is inputted into the parent software which exports the results for review and confirmation by a human expert.

AI-CVD® is a post-processing tool that works on existing and new CT scans.

AI-CVD® passes if the human expert approves the segmentation highlighted by the AI-CVD® module is correctly placed on the target anatomical region. For example, Software passes if the human expert sees the AI-CVD® cardiac chamber volumetry module highlighted the heart anatomy.

AI-CVD® fails if the human expert sees the segmentation highlighted by the AI-CVD® module is not correctly placed on the target anatomical region. For example, Software fails if the human expert sees the AI-CVD® cardiac chamber volumetry module highlighted the lungs anatomy or a portion of the sternum or any adjacent organs. Furthermore, Software fails if the human expert sees that the quality of the CT scan is compromised by image artifacts, severe motion, or excessive noise.

The user cannot change or edit the segmentation or results of the device. The user must accept or reject the segmentation where the AI-CVD® quantitative imaging measurements are performed.

Conditions of Use:



AI-CVD® is an AI-powered post-processing tool that works on non-contrast and contrast-enhanced CT scans of chest and abdomen.

Software and Model Detailed Description

AI-CVD® is a multi-module deep learning-based software platform developed to automatically segment and quantify a broad range of cardiovascular, pulmonary, musculoskeletal, and metabolic biomarkers from standard chest or whole-body CT scans. AI-CVD® system builds upon the open-source TotalSegmentator as its foundational segmentation framework, incorporating additional supervised learning and model training layers specific to each module's clinical task.

The original TotalSegmentator architecture utilizes a self-configuring neural network known as nnU-Net³, which was trained on 1,139 total body CT cases for general anatomical segmentation and 447 coronary CT angiography (CCTA) scans for high-resolution cardiac structure segmentation. Input data included both contrast-enhanced and non-contrast ECG-gated CT scans with 1.0 mm slice thickness, enabling robust cross-modality performance. Where available, matched contrast and non-contrast scans from the same subjects were registered and aligned to optimize anatomical consistency during training. Each module within AI-CVD® was further refined based on human expert knowledge for each particular measurement. Custom datasets were constructed for coronary artery calcium scoring, aortic and valvular calcifications, cardiac chamber volumetry, epicardial and visceral fat quantification, bone mineral density assessment, liver fat estimation, muscle mass and quality, and lung attenuation analysis. For each module, iterative model enhancement was applied: human reviewers evaluated model-generated segmentations and corrected any inaccuracies, and these corrections were looped back into the training process to improve performance and generalizability.

6. Indications for Use

AI-CVD® is an opportunistic AI-powered quantitative imaging tool that provides automated CT-derived anatomical and density-based measurements for clinician review. The device does not provide diagnostic interpretation or risk prediction. It is solely intended to aid physicians and other healthcare providers in determining whether additional diagnostic tests are appropriate for implementing preventive healthcare plans. AI-CVD® has a modular structure where each module is intended to report quantitative imaging measurements for each specific component of the CT scan. AI-CVD® quantitative imaging measurement modules include coronary artery calcium (CAC) score, aortic wall calcium score, aortic valve calcium score, mitral valve calcium score, cardiac chambers volumetry, epicardial fat volumetry, aorta and pulmonary artery sizing, lung density, liver density, bone mineral density, and muscle & fat composition.

Using AI-CVD® quantitative imaging measurements and their clinical evaluation, healthcare providers can investigate patients who are unaware of their risk of coronary heart disease, heart failure, atrial fibrillation, stroke, osteoporosis, liver steatosis, diabetes, and other adverse health



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conditions that may warrant additional risk assessment, monitoring or follow-up. AI-CVD® quantitative imaging measurements are to be reviewed by radiologists or other medical professionals and should only be used by healthcare providers in conjunction with clinical evaluation.

AI-CVD® is not intended to rule out the risk of cardiovascular diseases. AI-CVD® opportunistic screening software can be applied to non-contrast thoracic CT scans such as those obtained for CAC scans, lung cancer screening scans, and other chest diagnostic CT scans. Similarly, AI-CVD® opportunistic screening software can be applied to contrast-enhanced CT scans such as coronary CT angiography (CCTA) and CT pulmonary angiography (CTPA) scans. AI-CVD® opportunistic bone density module and liver density module can be applied to CT scans of the abdomen and pelvis. All volumetric quantitative imaging measurements from the AI-CVD® opportunistic screening software are adjusted by body surface area (BSA) and reported both in cubic centimeter volume (cc) and percentiles by gender reference data from people who participated in the Multi-Ethnic Study of Atherosclerosis (MESA) and Framingham Heart Study (FHS). Except for coronary artery calcium scoring, other AI-CVD® modules should not be ordered as a standalone CT scan but instead should be used as an opportunistic add-on to existing and new CT scans.



Comparison of Technological Characteristics & Intended Use to Predicate Device

The table below provides a summary of the technological characteristics of AI-CVD® in comparison to the predicate device. The indications for use for the predicate device are similar to the indications for the use of AI-CVD®. There are no major technological differences between the two systems that raise new issues of safety and/or effectiveness. Thus, AI-CVD® is substantially equivalent to the predicate and reference devices.

Feature	Subject Device AI-CVD®	Predicate 1 AutoChamber K240786	Predicate 2 Auto-BMD K213760	Reference 1 AI-Rad K183268	Reference 2 Imbio K230112	Reference 3 Imbio K141069
Indication for Use /Intended Use	<p>Estimate the volume of cardiac chambers, epicardial fat, aortic valves, ascending aorta, and pulmonary artery in non-contrast and contrast-enhanced CT scan images</p> <p>Estimate the percentage of liver voxels below 40HU in non-contrast CT scan images</p> <p>Estimate the percentage of lung voxels below -950 and above -250 in non-contrast CT scan images</p>	Estimate the volume of cardiac chambers in non-contrast and contrast-enhanced CT scan images	Estimate bone mineral density within the spine	<p>Estimate the volume of the heart</p> <p>Estimate the total volume of calcium in coronary arteries</p> <p>Estimate the maximum diameter of the aorta at typical landmarks</p>	Estimate coronary artery calcium score	Estimate pulmonary tissue density within the lungs



	<p>Estimate the volume of skeletal muscle, subcutaneous fat, and visceral fat in non-contrast CT scan images</p> <p>Estimate coronary artery calcium score, aortic wall and valve calcium scores, and mitral valve calcium score in non-contrast ECG-gate and non-gated chest CT scan images</p>					
Modality	CT scan images (DICOM)	CT scan images (DICOM)	CT scan images (DICOM)	CT scan images (DICOM)	CT scan images (DICOM)	CT scan images (DICOM)
Body Part	Chest / Abdomen	Chest	Chest / Abdomen	Chest	Chest	Chest



Automatic definition of ROIs	Yes, Deep Learning					
Device measures volume within the Region of Interest (ROI).	Yes	Yes	Yes	Yes	Yes	Yes
Device measures densities within the Region of Interest (ROI).	Yes	Yes	Yes	Yes	Yes	Yes
User	Healthcare Provider					
Operating System	Linux	Linux	Linux	Windows	Windows	Windows



Retrospective measurements from CT scans.	Yes	Yes	Yes	Yes	Yes	Yes

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-Life Testing

Not applicable for this software as a medical device.

Biocompatibility Testing

Not applicable for this software as a medical device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable for this software as a medical device.

Software Verification and Validation Testing

Software Verification and Validation testing was completed to demonstrate the safety and effectiveness of the device. Testing demonstrates AI-CVD® meets all its functional requirements and performance specifications.

Mechanical and Acoustic Testing

Not applicable for this software as a medical device.



Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Studies

Prospective clinical studies were not required to demonstrate the safety and effectiveness of the device. Instead, clinical validation studies were performed based upon retrospective analyses of AI-CVD® measurements performed on large population cohorts such as the Multi-Ethnic Study of Atherosclerosis (MESA) and Framingham Heart Study (FHS). All AI-CVD® quantitative imaging measurements were compared with measurements made manually by human experts or by gold standard reference tests to demonstrate the comparative safety and effectiveness of the device.

Coronary Artery Calcium Score

The AI-CVD® Coronary Artery Calcium (CAC) module provides fully automated Agatston CAC scoring, as well as an AI-derived calcium score based on relative density using an internal calibration reference. This approach enables detection of small and low-density calcified plaques that may not be captured by conventional fixed-threshold methods. Performance was evaluated outside of the MESA and FHS cohorts against manually measured Agatston scores using 913 consecutive, real-world coronary calcium screening CT scans acquired across three community imaging centers. The results demonstrated comparative safety and effectiveness between expert manual measurements and both the automated Agatston CAC scores and the AI-derived relative density-based calcium scores.

Aortic Wall and Aortic Valve Calcium Scores

The AI-CVD® Aortic Wall and Aortic Valve Calcification module provides automated quantification of calcified plaque within the thoracic aorta and calcification of the aortic valve from chest CT scans. Technical performance was evaluated through comparison with manual reference standards, with Bland–Altman agreement analyses demonstrating acceptable bias and reproducibility across imaging protocols.

Mitral Valve Calcium Score

The AI-CVD® Mitral Valve Calcification module provides automated quantification of calcification of the mitral valve from chest CT scans. Technical performance was evaluated through comparison with manual measurements, with agreement analyses demonstrating reproducible mitral valve calcium quantification across imaging protocols.



Cardiac Chambers Volume

The AI-CVD® Cardiac Chamber Volumetry module is based on previously FDA-cleared technology and utilizes established quantitative imaging measurement principles. The cardiac chamber volumetry module is AutoChamber™ (K240786), which has been reviewed and cleared by the FDA, and its inclusion within AI-CVD® does not raise new questions of effectiveness.

Epicardial Fat Volume

The AI-CVD® Epicardial Fat module provides automated volumetric quantification of epicardial adipose tissue from chest CT scans. Technical performance was further evaluated through agreement studies comparing AI-derived epicardial fat volumes with manual measurements and across non-contrast and contrast-enhanced CT acquisitions, demonstrating acceptable agreement and reproducibility.

Aorta and Main Pulmonary Artery Volume and Diameters

The AI-CVD® Aortic and Pulmonary Artery Size module provides automated measurements of thoracic aortic diameters and main pulmonary artery diameter from chest and abdominal CT scans. Agreement studies comparing AI-derived measurements of aortic and pulmonary artery measurements with manual reference measurements demonstrated low bias and comparable performance across gated and non-gated CT acquisitions. These findings support the reliability of AI-CVD® Aorta and Main Pulmonary Artery Volume and Diameter measurements.

Liver Attenuation Index

The AI-CVD® Liver Density module provides automated quantification of hepatic attenuation from chest CT scans. Agreement analysis comparing AI-derived liver attenuation measurements across imaging protocols demonstrated acceptable reproducibility.

Lung Attenuation Index

The AI-CVD® Lung Density module provides quantitative analysis of lung parenchymal attenuation from chest CT scans and within the field of view of cardiac CT scans. Agreement studies demonstrated reproducible lung density measurements across gated and non-gated CT acquisitions.



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Muscle and Visceral Fat

The AI-CVD® Thoracic Muscle and Fat Composition module provides quantitative assessment of skeletal muscle attenuation and adipose tissue composition from chest CT scans. Agreement analyses between AI-derived fat and muscle measurements demonstrated acceptable reproducibility across imaging protocols.

Bone Mineral Density

The AI-CVD® Bone Mineral Density module is based on previously FDA-cleared technology and utilizes established quantitative imaging measurement principles. The bone mineral density module is AutoBMD (K213760), which has been reviewed and cleared by the FDA, and its inclusion within AI-CVD® does not raise new questions of effectiveness.

8. Conclusions

The testing results demonstrate that AI-CVD® is as safe and effective as the predicate and reference devices. No new safety or effectiveness issues are raised by AI-CVD®.