



October 10, 2024

HeartLung Corporation
c/o Mark Scott
Regulatory Consultant
2450 Holcombe Blvd
Houston, Texas 77021

Re: K240786

Trade/Device Name: AutoChamber
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 7, 2024
Received: March 22, 2024

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the printed name and title.

Robert Ochs, Ph.D.

Director

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)
K240786

Device Name
AutoChamber

Indications for Use (Describe)

The AutoChamber software is an opportunistic AI-powered quantitative imaging tool that measures and reports cardiac chambers volumes comprising left atrium (LA), left ventricle (LV), right atrium (RA), right ventricle (RV), and left ventricular wall (LVW) from non-contrast chest CT scans including coronary artery calcium (CAC) scans and lung CT scans. AutoChamber is not intended to rule out the risk of a cardiovascular disease, and the results should not be used for any purpose other than to enable physicians to investigate patients that AutoChamber shows signs of enlarged heart (cardiomegaly), enlarged cardiac chambers, and left ventricular hypertrophy (LVH) whose conditions are otherwise missed by human eyes in non-contrast chest CT scans. AutoChamber similarly measures and reports LA, LV, RA, RV, and LVW in contrast-enhanced coronary CT angiography (CCTA) scans. Additionally, AutoChamber measures and reports cardiothoracic ratio (CTR) in both contrast and non-contrast CT scans where the entire thoracic cavity is in the axial field of view. AutoChamber quantitative imaging measurements are adjusted by body surface area (BSA) and are reported both in cubic centimeter volume (cc) and percentiles by gender using reference data from 5830 people who participated in the Multi-Ethnic Study of Atherosclerosis (MESA). AutoChamber 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 of the chest, such as CAC and lung CT scans, as well as CCTA scans.

Using AutoChamber quantitative imaging measurements and their clinical evaluation, healthcare providers can investigate asymptomatic patients who are unaware of their risk of heart failure, atrial fibrillation, stroke and other life-threatening conditions associated with enlarged heart, enlarged cardiac chambers, and LVH that may warrant additional risk-assessment or follow-up. AutoChamber 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



K240786

HeartLung Corporation
1124 W Carson St
The Lundquist Institute, MRL Building, Floor 3
Torrance, CA 90502

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
1124 W Carson St.
The Lundquist Institute, MRL Building, Floor 3
Torrance, CA 90502
Tel: (650) 448-8089
Contact: Dr. Morteza Naghavi
Date Prepared: September 20, 2023

2. Device

Subject Device: Automated Cardiac Chambers Volumetry Software
Trade Name: AutoChamber
Common Name: AutoChamber
Classification: Class II, 21 CFR 892.2050

Product Code: QIH
510(k) #: K240786

3. Predicate Device

Manufacturer: Imbio (Minneapolis, MN), LLC
Trade Name: Imbio RV/LV Software
Predicate 510(k): K203256

4. Reference Device

Manufacturer: Philips Medical Systems, (Cleveland), Inc.
Trade Name: Philips Comprehensive Cardiac Analysis (CCA) Plaque Assessment Tool
Reference 510(k): K092747

5. Device Description

General Description

The AutoChamber Software is an opportunistic AI-powered quantitative imaging tool that provides an estimate of cardiac volume, cardiac chambers volumes and left ventricular (LV) mass from non-contrast chest CT scans as well as contrast-enhanced chest CT scans. In addition to cardiac chambers volume and LV mass, AutoChamber measures and reports cardiothoracic ratio (CTR).



Intended Patient Population

Patients who underwent a chest CT scan.

Principles of Ops

AutoChamber Software reads a CT scan (in DICOM format) and extracts scan specific information like acquisition time, pixel size and scanner type. The AutoChamber Software uses an AI trained model to identify cardiac chambers in the field of view and measure the volume of each chamber including left atrium (LA), left ventricle (LV), right atrium (RA), right ventricle (RV), and LV wall (LVW). AutoChamber calculates the volume of each chamber as well as the corresponding total volume of all cardiac chambers and, if the field of view contains the entire width of the thoracic cavity in the axial view, it calculates and reports cardiothoracic ratio (CTR).

AutoChamber calculates the volume of each chamber based upon the volume of each pixel multiplied by the number of pixels in the region of interest per slice, multiplied by the number of slices included in each chamber's segmentation. The total volume per chamber is reported in cubic centimeters (CC). In addition to reporting the measured volume in CC per chamber, the AutoChamber report shows volumes adjusted by body surface area (BSA) and corresponding percentiles using reference data from 5830 people who participated in the Multi-Ethnic Study of Atherosclerosis (MESA). The default cut-off value for further investigations is the 75th percentile but it is optional and subject to provider's judgement.

AutoChamber does not provide a numerical individualized risk score/prediction or categorial assessment for whether an individual patient will develop cardiovascular disease over a specified period of time based on their percentile(s).

AutoChamber is a post-processing quantitative imaging software that works on existing and new CT scans. The AutoChamber Software is a software module installed by trained personnel only. The AutoChamber Software is executed via a parent software which provides the necessary input and visualizes the output data. The software itself does not offer user controls or access. The user cannot change or edit the segmentation or results of the device. The user must accept or reject the region where the cardiac chamber volume measurement is done. If rejected, the user must retry with a new series of images or conduct an alternate method to measure cardiac chamber volume. The expert's review solely pertains to the region of interest being properly located.

Software passes if the healthcare provider sees the cardiac chamber volumes and left ventricular mass highlighted by AutoChamber are correctly placed on the cardiac region based upon expert knowledge. Software fails if the healthcare provider sees the cardiac chamber volumes and left ventricular mass highlighted by AutoChamber are incorrectly placed outside of the cardiac anatomy. Software fails if the healthcare provider sees that the quality of the CT scan is compromised by image artifacts, motion, or excessive noise.

Conditions of Use:



The AutoChamber Software is an AI-powered post-processing software module that works on non-contrast and contrast-enhanced chest CT scans.

6. Intended Use

The AutoChamber software is an opportunistic AI-powered quantitative imaging tool that measures and reports cardiac chambers volumes comprising left atrium (LA), left ventricle (LV), right atrium (RA), right ventricle (RV), and left ventricular wall (LVW) from non-contrast chest CT scans including coronary artery calcium (CAC) scans and lung CT scans. AutoChamber is not intended to rule out the risk of a cardiovascular disease, and the results should not be used for any purpose other than to enable physicians to investigate patients that AutoChamber shows signs of enlarged heart (cardiomegaly), enlarged cardiac chambers, and left ventricular hypertrophy (LVH) whose conditions are otherwise missed by human eyes in non-contrast chest CT scans. AutoChamber similarly measures and reports LA, LV, RA, RV, and LVW in contrast-enhanced coronary CT angiography (CCTA) scans. Additionally, AutoChamber measures and reports cardiothoracic ratio (CTR) in both contrast and non-contrast CT scans where the entire thoracic cavity is in the axial field of view. AutoChamber quantitative imaging measurements are adjusted by body surface area (BSA) and are reported both in cubic centimeter volume (cc) and percentiles by gender using reference data from 5830 people who participated in the Multi-Ethnic Study of Atherosclerosis (MESA). AutoChamber 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 of the chest, such as CAC and lung CT scans, as well as CCTA scans.

Using AutoChamber quantitative imaging measurements and their clinical evaluation, healthcare providers can investigate asymptomatic patients who are unaware of their risk of heart failure, atrial fibrillation, stroke and other life-threatening conditions associated with enlarged heart, enlarged cardiac chambers, and LVH that may warrant additional risk-assessment or follow-up. AutoChamber 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.

Comparison of Technological Characteristics & Intended Use to Predicate Device

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



Feature	Subject Device AutoChamber Software K240786	Predicate Device: Imbio RV/LV K203256	Reference Device: Philips Comprehensive Cardiac Analysis (CCA) K092747
Indication for Use/Intended Use	Use an artificial intelligence algorithm to identify the location and measure the volume of cardiac chambers.	Use an artificial intelligence algorithm to identify the location and measurements of the cardiac ventricles.	Analyzing cardiac CT data and measuring cardiac chamber sizes and coronary plaque analysis.
Modality	CT scan images (DICOM)	CT scan images (DICOM)	CT scan images (DICOM)
Body Part	Heart / Chest	Heart / Chest	Heart
Automatic definition of ROIs	Yes, Deep Learning	Yes, Deep Learning	Yes, endoluminal and epiluminal segmentation
Device provides volume in CC	Yes	Yes	Yes
User	Healthcare Provider	Healthcare Provider	Healthcare Provider
Operating System	Linux	Windows	Windows
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	CT scan images can be selected and inputted to the software



Automation	Software automatically identifies cardiac chambers, estimates and reports the volume of each chamber	Software automatically identifies cardiac left and right ventricles and reports RV/LV ratio	Software automatically identifies cardiac chambers, estimates the volumes and reports RV/LV ratio
------------	--	---	---

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 the AutoChamber Software 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 is based upon retrospective analyses of AutoChamber software measurements in existing prospective studies databases were carried out. In one study AutoChamber results were compared with measurements previously made by cardiac MRI in 5003 cases who underwent both non-contrast cardiac CT scan and cardiac MRI. Furthermore, AutoChamber results were compared in 1433 patients with paired non-



K240786

HeartLung Corporation
1124 W Carson St
The Lundquist Institute, MRL Building, Floor 3
Torrance, CA 90502

contrast and contrast-enhanced cardiac CT scans. In yet another study, AutoChamber results were compared in 171 patients who underwent both ECG-gated cardiac CT scan and non-gated full chest lung scan. Additionally, clinical performance was established based on direct comparison of AutoChamber results with Reference device (K060937) in 131 cases who underwent both measurements.

8. Conclusions

The body of testing summarized above indicates that the AutoChamber Software performs as intended and supports a determination of substantial equivalence to the predicate device. The testing above demonstrates that the AutoChamber Software is as safe and effective as the predicate device. No new safety or effectiveness issues are raised by the AutoChamber Software.