July 29, 2022

HeartLung Corporation
℅ Lauren Lee
Regulatory Consultant
1124 W Carson St
TORRANCE CA 90502

Re: K213760
Trade/Device Name: ABMD Software
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone Densitometer
Regulatory Class: Class II
Product Code: KGI
Dated: June 22, 2022
Received: June 29, 2022

Dear Lauren Lee:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Laurel Burk
Assistant Director
DHT8B: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213760

Device Name
ABMD Software

Indications for Use *(Describe)*
The Automated Bone Mineral Density Software Module (ABMD) is a post-processing AI-powered software intended to measure bone mineral density (BMD) from existing CT scans by averaging Hounsfield units in the trabecular region of vertebral bones. ABMD is not intended to replace DXA or any other tests dedicated to BMD measurement. It is solely designed for measuring BMD in existing CT scans or CT scans ordered for reasons other than BMD measurement. In summary, ABMD 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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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: November 24, 2021

2. **Device**

   Subject Device: Automated Bone Mineral Density Software
   Trade Name: ABMD Software
   Common Name: ABMD Software
   Classification: Class II, 21 CFR 892.1170
   Product Code: KGI

3. **Predicate Device**

   Manufacturer: Mindways
   Trade Name: QCT Bone Mineral Density Analysis Software
   Predicate 510(k): K894854
   Classification: Class II, 21 CFR 892.1170
   Product Code: KGI

4. **Reference Device**

   Manufacturer: Mindways
   Trade Name: QCT Pro Asynchronous Calibration Module, CliniQCT
   Predicate 510(k): K140342
   Classification: Class II, 21 CFR 892.1170
   Product Code: KGI

5. **Device Description**

General Description

The Automated Bone Mineral Density (ABMD) Software is a software module that estimates bone mineral density in the vertebral bones by averaging Hounsfield Units (HU) in the trabecular

area. ABMD Software is a post-processing software that works on existing CT scans. ABMD Software measurements are to be reviewed by radiologists and should be used by healthcare providers in conjunction with clinical evaluation.

Intended Patient Population

ABMD Software is for post-processing analysis of bone mineral density in people who underwent a CT scan that includes vertebral bone.

Principles of Ops

ABMD Software reads a CT scan (in DICOM format) and extracts patient-specific metadata such as age, gender, and scan specific information like acquisition time, pixel size and scanner type. The ABMD Software uses an AI trained model to segment out vertebral bones in the field of view and subsequently measures the average of the Hounsfield unit, HU, in a cylinder volume within the trabecular tissue of each vertebral bone without including the cortical bone. The bone mineral density (BMD) is calculated by the mean of those averages for vertebral bones found in the field of view. Subsequently, the Z-score and T-scores are calculated based on the age and gender of the person and the calibration factor for the CT scan. The snapshots of the spinal bones and measured area along with the average HU and the scores are exported for review and confirmation by a human expert.

Software will output the segmentation of trabecular bone used in calculation of BMD as determined by the sample volume being a minimum of 1 pixel away from the cortical bone.

Software passes if the sample volume is at least 1 pixel away from the cortical border.

Software fails if the sample volume crosses or intersects with the cortical border.

The end user cannot change or edit the segmentation or results of the device. The end user must accept or reject the region where the BMD measurement is done. If rejected, the end user must conduct an alternate method such as manual measurement using the same methods described in QCT-based manual measurement of BMD.

This device is not intended to replace DXA scanners. It is only intended to be used on the existing CT scans or CT scans ordered for reasons other than measuring BMD so that it will prevent extra radiation dose being introduced to the patients.

Conditions of Use:

The ABMD Software is a post-processing software module that only works on existing CT scans that include spinal bones.

6. Intended Use

The Automated Bone Mineral Density (ABMD) Software is a post-processing AI-powered software intended to measure bone mineral density (BMD) from existing CT scans by averaging Hounsfield units in the trabecular region of vertebral bones. ABMD Software is not intended to replace DXA or any other tests dedicated to BMD measurement. It is solely designed for measuring BMD in existing CT scans or CT scans ordered for reasons other than BMD measurement. In summary, ABMD Software 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.

7. Comparison of Technological Characteristics & Intended Use to Predicate Device

The table below provides a summary of the technological characteristics of the ABMD 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 ABMD Software. There are no major technological differences between the two systems that raise new issues of safety and/or effectiveness. Thus, the ABMD Software is substantially equivalent to the predicate device.

Feature	**Subject Device ABMD Software**	**Predicate Device QCT Bone Mineral Density Analysis Software K894854**	**Reference Device QCT Pro Asynchronous Calibration Module, CliniQCT K140342**	**Summary**
Indication for Use/Intended Use	Estimate bone mineral density within the spine.	Estimate bone mineral density within the spine.	Estimate bone mineral density within the spine.	Equivalent.
Modality	CT scan images (DICOM)	CT scan images (DICOM)	CT scan images (DICOM)	Equivalent.
Device provides estimates of	Yes	Yes	Yes	Equivalent.

bone mineral density from the spine.				
Device provides the bone mineral density value.	Yes	Yes	Yes	Equivalent.
Device provides Z-score.	Yes	Yes	Yes	Equivalent.
Device provides T-score.	Yes	Yes	Yes	Equivalent.
User	Healthcare Providers	Healthcare Providers	Healthcare Providers	Equivalent.
Operating System	Linux	Windows	Windows	Equivalent, software function is independent from operating system.
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.	Equivalent.
Automatic Averaging Hounsfield Units	Software automatically measures and averages Hounsfield units in the trabecular	Software automatically measures and averages Hounsfield units in the trabecular	Software automatically measures and averages Hounsfield units in the trabecular	Equivalent.

	region of spinal bones.	region of spinal bones.	region of spinal bones.	
Calibration	Inputting CT scanner-specific calibration factor is required. Software outputs calibrated BMD score.	Simultaneous scanning of calibration phantom is required. Software outputs calibrated BMD score.	Asynchronous scanning of calibration phantom is required. Software outputs calibrated BMD score.	Equivalent. Software provides measurements corrected for calibration data.

8. 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 ABMD Software meets all its functional requirements and performance specifications.

The ABMD Software strongly correlated with manual QCT-based BMD measurement. The scatter plot and regression lines show the range of bias to be limited and display a very strong correlation between BMD measured by manual method versus ABMD Software ($r = 0.97$, $p<0.01$). The ABMD Software also correlated with DXA BMD measurement ($r = 0.72$, $p<0.01$). A summary of two studies performed is listed below.

ABMD Software Performance Studies

	Study 1	**Study 2**
Reference Dataset	993 quantitative CT (QCT) readings of a cohort of asymptomatic cases who underwent CT scans.	172 asymptomatic cases who underwent whole-body DXA scans as well as CT scans.
Truthing Process	QCT BMD, T-score, and Z-score values derived from manual measurement by trained operators.	DXA scans derived T-score, and Z-score values plus QCT BMD, T-score, and Z-score values derived from manual measurement by trained operators.
Analysis methods	Pearson Correlation, Deming Regressions, and Bland Altman Agreement	Pearson Correlation, Deming Regressions, and Bland Altman Agreement
Results	Strong correlations and agreements were found between manual QCT and ABMD Software	Strong correlations and agreements were found between manual QCT and ABMD Software. Modest but significant correlations and agreement were found between DXA, and ABMD Software.

Significant correlations between BMD measurements by DXA and ABMD Software were found ($r = 0.72$, $p<0.01$) which closely matched the correlations reported in literature between DXA and manual QCT ($r=0.5$ to $r=0.75$) measurements. While DXA BMD measurements at Ward Triangle correlate well with QCT BMD measurement in vertebral bones, the QCT measurement is exclusively focused on the trabecular bone tissue, as compared to DXA's combined measurement of cortical and trabecular bone tissues. Therefore, QCT based BMD measurement using ABMD Software is more specific to trabecular bone tissues and does not impose any additional safety or effectiveness concerns when compared to the predicate device.

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

Clinical testing was not required to demonstrate the safety and effectiveness of the device. Instead, substantial equivalence is based upon software verification and validation testing, or benchtop performance testing of the software as a medical device.

9. Conclusions

The body of testing summarized above indicates that the ABMD Software performs as intended and is substantially equivalent to the predicate device. The testing above demonstrates that the ABMD Software is as safe and effective as the predicate device. No new safety or effectiveness issues are raised by the ABMD Software.