Exo Inc
Jacqueline Murray
Senior Regulatory Affairs Specialist
4201 Burton Drive
Santa Clara, CA 95054

November 17, 2023

Re: K232501
Trade/Device Name: AI Platform (AIP001)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: October 25, 2023
Received: October 26, 2023

Dear Jacqueline Murray:

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.

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
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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)*
K232501

Device Name
AI Platform (AIP001)

Indications for Use *(Describe)*
The AI Platform is intended for noninvasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of adult patients with suspected disease. The device is intended to be used on images from adult patients.

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.

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510(k) Summary K232501

General Information

510(k) Sponsor	Exo Imaging
Address	4201 Burton Drive Santa Clara, CA 95054
Correspondence Person	Jacqueline Murray
Contact Information	jmurray@exo.inc Cell: +1 236 838-5056
Date Prepared	September 21st, 2023

Proposed Device

Proprietary Name	AI Platform (AIP001)
Common Name	AI Platform
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Predicate Device

Proprietary Name	LVivo Software Application
Premarket Notification	K210053
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Reference Device

Proprietary Name	Lumify Diagnostic Ultrasound System
Premarket Notification	K223771
Classification Name	Ultrasonic pulsed doppler imaging system
Regulation Number	21 CFR 892.1550
Product Code	IYN, IYO, ITX, QIH
Regulatory Class	II

Device Description

Exo AI Platform is a software as a medical device (SaMD) that helps qualified users with image-based assessment of ultrasound examinations in adult patients. It is designed to simplify workflow by helping trained healthcare providers evaluate, quantify, and generate reports for ultrasound images. The device is intended to generate images and a report that can be reviewed in a typical standard of care setting.

AI Platform takes as an input imported Digital Imaging and Communications in Medicine (DICOM) images from ultrasound scanners of a specific range and allows users to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease. It provides users with a specific toolset for viewing ultrasound images of the lung and heart, placing landmarks, and creating reports.

Key features of the software are

- LVEF AI: an AI-assisted tool for quantification of ejection fraction on cardiac ultrasound images.
- Lung AI: an AI-assisted tool to suggest presence of lung structures and artifacts on ultrasound images.

Exo AI Platform does not perform any function that could not be accomplished by a trained user manually. It's important to note that patient management decisions should not be made solely on the results of the AI Platform analysis.

Indications for Use

The AI Platform is intended for noninvasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of adult patients with suspected disease. The device is intended to be used on images from adult patients.

Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	**Subject Device** Exo AI Platform	**Predicate Device** LVivo Software Application (**K210053**)	**Reference Device** Lumify Diagnostic Ultrasound System (**K223771**)
Image input	Complies with DICOM Standard	Same as subject device	Same as subject device
Scan type	Single and Multi-frame ultrasound images	Same as subject device	Same as subject device

Feature/ Function	**Subject Device** Exo AI Platform	**Predicate Device** LVivo Software Application (**K210053**)	**Reference Device** Lumify Diagnostic Ultrasound System (**K223771**)
Image display mode	Static	Same as subject device	Same as subject device
Image navigation and manipulation tools	Slice-scroll, pane layout, reset	Same as subject device	Same as subject device
Image review	Yes, capable of reviewing all frames of multi-frame (multi-slice) images	Same as subject device	Same as subject device
Principle of Operation and Technology	Ultrasound image processing software implementing artificial intelligence including non-adaptive machine learning algorithms trained with clinical data intended for non-invasive analysis of ultrasound data	Same as subject device	Same as subject device
AI Algorithm	Deep Convolutional Neural Networks for Segmentation or Landmark Detection	Same as Subject Device	Same as subject device
Manual Adjustments or Editing by User Allowed	Yes	Same as Subject Device	Same as Subject Device
Anatomical Sites	Heart, Lungs	Heart, Bladder	Lungs
Ejection Fraction Measurement Views	AP4, AP2, Bi-plane, PLAX	AP4, AP2, Bi-plane	No
Non Cardiac functions	A-lines, B-lines	Bladder Volume	B-lines
Report creation	Yes	Same as subject device	Same as subject device

Performance Data

Safety and performance of the AI Platform has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/AC:2015 - Medical device software – Software life cycle processes,* FDA's 'Content of Premarket Submissions for Device Software Functions'' Guidance for Industry and Food and Drug Administration Staff Document issued on June 14, 2023 and FDA Guidance (June 2022) *"Technical performance assessment of quantitative imaging in radiological device premarket submissions".*

Validation Performance Testing

The clinical performance of the AI platform was successfully evaluated on a test data encompassing diverse demographic variables, including gender, age (ranging from 20 to 96), BMI (ranging from 15.3 to 52.8), and ethnicity from multiple clinical sites in metropolitan cities with diverse racial patient populations. The Lung function was evaluated with 125 subjects, on images acquired during a routine clinical practice from cart-based and portable ultrasound devices (with frequency ranging from 1.5 to 7 MHz). The LVEF function was evaluated with 151 subjects, on images acquired from cart-based and portable ultrasound devices (with frequency ranging from 1.2 to 4 MHz).

The test data was entirely separated from the training/validation datasets and was not used for any part of the training. To ensure data separation and generalizability, the data sources used in the test set are chosen to be different from the data sources used in the training set. We also established auditability measures, by assigning a unique identification number to each study and its corresponding images.

The ground truth for ejection fraction (reference data) was obtained as the average ejection fraction measurement of three experts. Performance was assessed by calculating the intraclass correlation coefficient (ICC) and ejection fraction root mean square difference (RMSD).

The measurement accuracy of AI Platform for cardiac ultrasound images compared with reference data is summarized in **Table 1** below:

Table 1: Summary of AI Platform accuracy and reliability for cardiac ultrasound images

Subgroup (View)	**ICC** (95% CI)	**RMSD** (95% CI)
Ejection Fraction Parasternal Long-axis	**0.93** (0.89 – 0.96)	**6.12** (5.30 – 8.36)
Ejection Fraction Apical Biplane	**0.95** (0.90 – 0.98)	**4.81** (3.99 – 7.25)
Ejection Fraction Apical (AP4) Single Plane	**0.92** (0.88 – 0.95)	**6.06** (5.27 – 8.20)
Ejection Fraction Apical (AP2) Single Plane	**0.92** (0.87 – 0.95)	**6.25** (5.33 – 8.82)
All	**0.93** (0.91 – 0.95)	**5.90** (5.35 – 7.23)

The ground truth of the presence of A-line was determined by consensus of two or more experts. Performance was assessed by measuring the agreement using Cohen's kappa coefficient (κ).
The ground truth of B-line counts was determined as the average of B-line counts from three experts. Performance was assessed by calculating the intraclass correlation coefficient (ICC). The reliability of AI platform for lung ultrasound images compared with reference data is summarized in **Table 2** below:

Table 2: Summary of AI Platform reliability for lung ultrasound images

	Reliability
A-lines	Kappa = 0.84
B-lines	ICC = 0.97

The device performance was also assessed across a wide range of Ultrasound manufacturer, demographic subgroups, (including gender and BMI) and clinical confounders present including heart failure with reduced ejection fraction, Covid-19, Chronic obstructive pulmonary disease (COPD), Pneumonia, Pulmonary Edema, Coronary artery disease (CAD) and Cardiomyopathy. The evaluation concluded that the device performance was consistent among clinically meaningful subgroups.

Conclusions

Exo's AI Platform is substantially equivalent in intended use, design, principles of operation, technological characteristics, and safety features to the predicate device. There are no different questions of safety and/or effectiveness introduced by the AI Platform when used as intended.