August 5, 2024

Exo Imaging
Jacqueline Murray
Senior Regulatory Affairs Specialist
4201 Burton Drive
Santa Clara, California 95054

Re: K240953
Trade/Device Name: AI Platform 2.0 (AIP002)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: July 2, 2024
Received: July 3, 2024

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device,

or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

for

Jessica Lamb, Ph.D.
Assistant Director
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

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)*
K240953

Device Name
AI Platform 2.0 (AIP002)

Indications for Use *(Describe)*
AI Platform 2.0 is intended for noninvasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease. In addition, it can provide Quality Score feedback to assist healthcare professionals, trained and qualified to conduct echocardiography and lung ultrasound scans in the current standard of care while acquiring ultrasound images. The device is intended to be used on images of 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.

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K240953

510(k) Summary

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	April 08, 2024

Proposed Device

Proprietary Name	AI Platform 2.0 (AIP002)
Common Name	AI Platform 2.0
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Predicate Device

Proprietary Name	LVivo IQS
Premarket Notification	K222970
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Reference Device 1

Proprietary Name	Caption Guidance
Premarket Notification	DEN190040
Classification Name	Image Acquisition And/Or Optimization Guided by Artificial Intelligence
Regulation Number	21 CFR 892.2100

Product Code	QJU
Regulatory Class	II

Reference Device 2

Proprietary Name	AI Platform
Premarket Notification	K232501
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Device Description

Exo AI Platform 2.0 (AIP 2.0) 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. AIP 2.0 takes as an input in the Digital Imaging and Communications in Medicine (DICOM) format 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. In addition, it provides frame and clip quality score in real-time for the Left Ventricle from the four-chamber apical and parasternal long axis views of the heart and lung scans. In addition, the AI modules are provided as a software component to be integrated by another computer programmer into their legally marketed ultrasound imaging device. Essentially, the Algorithm and API, which are modules, are medical device accessories.

Key features of the software are

- Lung AI: An AI-assisted tool for suggesting the presence of lung structures and artifacts on ultrasound images, namely A-lines and B-lines. Additionally, a per-frame and per-clip quality score is generated for each lung scan.
- Cardiac AI: An AI-assisted tool for the quantification of Left Ventricular Ejection Fraction (LVEF), Myocardium wall thickness (Interventricular Septum (IVSd), Posterior wall (PWd)), and IVC diameter on cardiac ultrasound images. Additionally, a per-frame and per-clip quality score is generated for each Apical and PLAX cardiac scan.

Warning:

It's important to note that patient management decisions should not be made solely on the AI Platform 2.0 analysis results. Users are fully responsible for ensuring scan quality and making diagnoses. Images obtained through the use of Quality AI should be interpreted exclusively by certified healthcare professionals. It is also imperative that a qualified healthcare professional reviews the data, ensuring its adequacy and appropriateness for the intended diagnosis or management.

Indications for Use

AI Platform 2.0 is intended for noninvasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease. In addition, it can provide Quality Score feedback to assist healthcare professionals, trained and qualified to conduct echocardiography and lung ultrasound scans in the current standard of care while acquiring ultrasound images. The device is intended to be used on images of adult patients.

Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	**Subject Device** Exo AI Platform 2.0	**Predicate Device: LVivo IQS (K222970)**	**Reference Device 1: Caption Guidance (DEN190040)**	**Reference Device 2: AI Platform (K232501)**
Scan type	Single and Multi-frame ultrasound images	Same as subject device	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	Same as subject device

Feature/ Function	**Subject Device** Exo AI Platform 2.0	**Predicate Device: LVivo IQS (K222970)**	**Reference Device 1: Caption Guidance (DEN190040)**	**Reference Device 2: AI Platform (K232501)**
AI Algorithm	Deep Convolutional Neural Networks for Segmentation, Landmark Detection and Classification	Same as subject device	Same as subject device	Same as subject device
Anatomical Sites	Heart, Lungs	Heart, Bladder	Heart	Heart, Lungs
Cardiac Measurements	LVEF IVC Minimum diameter on inspiration and Maximum diameter on expiration Myocardium wall thickness (Interventricular Septum and Posterior wall) from Plax view	LVEF, GLS RV size and function: Fractional Area Change (FAC), Free Wall Strain (FWS), Tricuspid annular plane systolic excursion (TAPSE)	No	LVEF
Non Cardiac AI modules	Absence/presence of A-lines B-lines count	Bladder Volume	No	Absence / presence of A-lines B-lines count
Real time feedback on quality	Yes	Same as subject device	Same as subject device	No
Retrospectively recording of Diagnostic quality clip	Yes	No	Same as subject Device	No

Feature/ Function	Subject Device Exo AI Platform 2.0	Predicate Device: LVivo IQS (K222970)	Reference Device 1: Caption Guidance (DEN190040)	Reference Device 2: AI Platform (K232501)
AI modules are an accessory to compatible general purpose diagnostic ultrasound systems	Yes	Same as subject device	Same as subject device	No

Performance Data

Safety and performance of the AI Platform 2.0 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 2.0 was successfully evaluated on test data encompassing diverse demographic variables, including gender, age, and ethnicity from multiple clinical sites in metropolitan cities with diverse racial patient populations. The test data was entirely separated from the training/tuning datasets and was not used for any part of the training/tuning. We also established auditability measures, by assigning a unique identification number to each study and its corresponding images.

The left ventricle Wall thickness AI and IVC AI were each evaluated on scans of 100 subjects, on images acquired from cart-based and portable ultrasound devices. The ground truth for all measurements were obtained as the average measurement of three experts. Performance was assessed by calculating Inter class correlation (ICC) between the AI and the ground truth.

The performance of AI Platform 2.0 for wall thickness and IVC compared with reference data is summarized in **Table 1** below:

Table 1: Summary of AI Platform performance for left ventricle wall thickness and IVC measurement

	Measurement	**ICC** (95% CI)
LV Wall thickness	InterVentricular Septum (IVSd)	**0.93** (0.89 – 0.96)
	Posterior Wall (PWd)	**0.94** (0.89 – 0.97)
Inferior vena cava (IVC)	IVC Dmin	**0.93** (0.90 – 0.95)
	IVC Dmax	**0.94** (0.90 – 0.96)

The validation of Quality AI consists of validating on:

a. Data previously acquired from 184 patients from various ultrasound devices and various cardiac pathologies, compared to quality rating by experienced sonographers on each frame and the entire clip. Total of 226 clips (29,732 frames) were used in this test. The overall agreement between the Quality AI and quality rated by the experienced sonographers was ICC = 0.94 (95% CI .94 – .95) for frames and ICC = 0.94 (95% CI .92 – .95) for clips.
b. Data acquired after using the image and clip Quality AI in real time while scanning Lung, Apical 4 chamber, and Parasternal Long Axis views of the heart. In total, 396 lung and cardiac scans were done by 26 users with a wide range of ultrasound experience in POC settings, including 18 novice users who received two hours of training. 98.3% of the clips rated as ACEP quality of 3 or above by expert readers, also received at least “Minimum criteria met for diagnosis” image quality by Clip Quality AI. Additionally, 98.0% of scans that were considered as “Minimal criteria met for diagnosis” or “good” by Quality AI were also deemed diagnostic by experts (ACEP score of 3 or higher).

Predetermined Change Control Plan

A Predetermined Change Control Plan (PCCP) is included with AI Platform 2.0. The PCCP specifies anticipated software modifications, implementation methods and validation criteria that will be used to implement the software modifications in a controlled manner and ensure the subject device remains as safe and effective as the predicate.

The PCCP includes a specific list of anticipated software modifications which are summarized in the table below, as well as a Modification protocol describing the verification and validation activities that will support these planned modifications. The modification protocol incorporates impact assessment considerations and specifies requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data segregation/re-use practices.

Specific test methods are specified in the PCCP to establish substantial equivalence relative to AI Platform 2.0, and include sample size determination, analysis methods, and acceptance criteria. Original and additional validation data will be analyzed to ensure the datasets are representative of the intended use population. To ensure validation test datasets are representative of the intended use population, each will meet minimum demographic requirements.

A summary of these software modifications, test methods, necessary performance requirements, and impact assessment, are presented in the table below:

Modification	Rationale	Testing Methods	Impact Assessment
(A) Modification to architecture, pre/post processing	The AI models in AI Platform 2.0 may be modified in a focused and bound manner, to improve accuracy, efficiency, and adaptability while maintaining the safety and efficacy of the device.	Substantial equivalence in performance matrices as compared to the AI Platform 2.0. Non-inferiority margins in alignment with FDA recommendations will be used to ensure the new device remains safe and effective without any such change compared with the original device and the last modified version of the device.	Improved accuracy and/or efficiency metrics for AI model performance. Benefit-Risk Analysis: Benefit: Enhanced performance; Improved efficiency and scalability. Risk: Reduction in clinical performance Risk Mitigation: The risks of overfitting and generalizability are mitigated by conducting cross-validation, data augmentation, and hyper parameter tuning in internal training procedures. The final validation is performed using non-inferiority analysis according to the established clinical protocol to ensure baseline performance is maintained and improvements are realized before modifications are committed and released.
(B) Introduction of new training data	The training dataset of the AI models may be augmented with a broader and more diverse range of imaging data to enhance model robustness, reduce bias, improve generalizability, and respond effectively to real-world feedback.	Substantial equivalence in performance matrices as compared to the AI Platform 2.0. Non-inferiority margins in alignment with FDA recommendations will be used to ensure the new device remains safe and effective without any such change compared with the original device and the last modified version of the device	Improved model generalizability for AI model outputs displayed to users. Benefit-Risk Analysis: Benefit: Improved model robustness, reduced bias, enhanced generalizability, and responding to real world feedback. Risk: Reduction in clinical performance Risk Mitigation: The risks of overfitting and generalizability are mitigated by conducting cross-validation, data augmentation, and hyper parameter tuning in internal training procedures. The final validation is performed using non-inferiority analysis according to the established clinical protocol to ensure baseline

			performance is maintained and improvements are realized before modifications are committed and released.

The input and output data by the network will remain unchanged and model re-training will be conducted manually, not automatically.
Exo shall communicate AI Platform 2.0 software changes, performance changes, and labeling changes to end-users via customer and software update notifications.

The benefits and risks of each of the above modifications, independently and combined, including risks of social harm have been assessed, and the overall collective impact of implementing modifications remains low.
The activities proposed within the Modification Protocol will continue to reasonably ensure the safety and effectiveness of the device, and all modifications will maintain the AI Platform device within its stated intended use and indications for use.

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.

The clinical performance of the AI Platform 2.0 product was successfully evaluated on test data encompassing diverse demographic variables, including gender, age and ethnicity from multiple clinical sites in metropolitan cities with diverse racial patient populations.

The A-Line, B-line and LVEF algorithms did not change during the development of the AI Platform 2.0 product and remain as per the cleared algorithms in K232501.

The activities proposed within the Modification Protocol will continue to reasonably ensure the safety and effectiveness of the product, and all modifications will maintain the AI Platform device within its stated intended use and indications for use.