February 24, 2026

Exo Imaging
Dornoosh Zonoobi
VP of AI
4201 Burton Dr.
Santa Clara, California 95054

Re: K260217
Trade/Device Name: AI Platform 2.2 (AIP002)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: January 23, 2026
Received: January 23, 2026

Dear Dornoosh Zonoobi:

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 Management System Regulation (QMSR) regulation (21 CFR Parts 4 and 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,

for

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260217

Please provide the device trade name(s).

AI Platform 2.2 (AIP002)

Please provide your Indications for Use below.

AI Platform 2.2 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, abdominal, 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary K260217

Purpose of the Submission

This Special 510(k) submission is intended to support a limited modification to the legally marketed AI Platform 2.0 (K240953). The modification extends the existing Quality AI functionality to support additional abdominal ultrasound views (upper quadrants and pelvic). The modification does not change the intended use, clinical role, core technology, software architecture, user workflow, or risk profile of the device.

General Information

510(k) Sponsor	Exo Imaging
Address	4201 Burton Drive Santa Clara, CA 95054
Correspondence Person	Dornoosh Zonoobi
Contact Information	dornoosh@exo.inc Cell: +1 780 717 4817
Date Prepared	January 23, 2026

Proposed Device

Proprietary Name	AI Platform 2.2 (AIP002)
Common Name	AI Platform 2.2
Premarket Notification	K260217
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Predicate Device

Proprietary Name	AI Platform 2.0 (AIP002)
Premarket Notification	K240953
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Device Description

Exo AI Platform 2.2 (AIP 2.2) 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 2.2 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, Abdominal Upper Quadrant and Pelvic views, and lung scans. The AI modules are provided as software components 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.
- 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.
- Quality AI: An AI tool designed to assess ultrasound per frame and per clip quality across Cardiac (A4C and PLAX), Lung, and Abdominal (Upper Quadrants and Pelvic) views.

Warning:

It is important to note that patient management decisions should not be made solely on the AI Platform 2.2 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.

Elements Unchanged from the Predicate Device:

The following aspects remain unchanged from the predicate device (AI Platform 2.0, K240953)

- Intended use and patient population
- AI architecture and system design
- Data inputs, outputs, and user workflow
- Labeling, warnings, and clinician responsibility
- Risk classification and mitigation strategies

Indications for Use

AI Platform 2.2 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, abdominal, 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.

Description of the Modification

The modification extends the existing Quality AI module to accept and assess two additional abdominal ultrasound views: upper-quadrant and pelvic. No changes were made to the intended use, core technology, system architecture, data inputs, outputs, or user workflow.
The predicate device (AI Platform 2.0, K240953) includes a Predetermined Change Control Plan (PCCP). The device continues to contain this PCCP; however, the subject modifications described in this submission are outside the scope of the PCCP.

Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	Subject Device Exo AI Platform 2.2	Predicate Device: Exo AI platform 2.0 (K240953)
Indications for Use	AI Platform 2.2 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, abdominal, 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.	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.
Scan type	Single and Multi-frame ultrasound images	Same as subject device. No changes were made.

Feature/ Function	Subject Device Exo AI Platform 2.2	Predicate Device: Exo AI platform 2.0 (K240953)
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. No changes were made.
AI Algorithm	Deep Convolutional Neural Networks for Segmentation, Landmark Detection and Classification	Same as subject device. No changes were made.
Cardiac Measurements	LVEF IVC Minimum diameter on inspiration and Maximum diameter on expiration Myocardium wall thickness (Interventricular Septum and Posterior wall) from Plax view	Same as subject device. No changes were made.
Non Cardiac AI modules	Absence/presence of A-lines B-lines count	Same as subject device. No changes were made.
Real-time feedback on quality	Yes	Same as subject device. No changes were made.
Anatomical Sites for Quality AI	Heart, Lungs, and Abdomen	Heart, Lungs
Retrospectively recording of Diagnostic quality clip	Yes	Same as subject device. No changes were made.
AI modules are an accessory to compatible general purpose diagnostic ultrasound systems	Yes	Same as subject device. No changes were made.

Risk Analysis Summary

A risk analysis was conducted for the AI Platform 2.2 device in accordance with Exo's existing risk management process and ISO 14971, to assess the potential impact of adding support for abdominal views. The primary identified hazard for the Quality AI functionality - misclassification of image quality - remains unchanged from that identified for the predicate device.

New risk control measures were implemented to address potential risks associated with the added abdominal views. Following implementation and verification of these controls, residual (post-mitigation) risk levels remain consistent with those of the predicate device. The modification does not introduce new hazard types beyond those previously identified, and does not raise new questions of safety or effectiveness. The overall benefit-risk profile remains consistent with that of the predicate device.

Performance Data

Safety and performance of the AI Platform 2.2 has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. 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".* All verification and validation activities confirmed that the modification did not impact the core functionality, performance, or safety of the system.

Validation Performance Testing and Results

Validation of the AI Platform 2.2 followed the same methodology, acceptance criteria, and expert-reference framework used for the predicate device and was applied to the additional abdominal views. The performance 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 validation of Abdominal Quality AI consists of validating on:

a. Data previously acquired from 184 patients from various ultrasound devices and various abdominal pathologies, compared to quality rating by experienced sonographers on each frame and the entire clip. A total of 200 clips (29,371 frames) were used in this test. The overall agreement between the Quality AI and quality rated by the experienced sonographers was ICC = 0.94 (.94 – .95) for frames and ICC = 0.95 (.94 – .96) for clips.

b. Data acquired using the image and clip Quality AI in real time while scanning the pelvic and upper quadrant views of the abdomen. In total, 186 abdomen scans were acquired by 12 users with a wide range of ultrasound experience in POC settings, including 8 novice users who received two hours of training. 96.6% 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, 96.1% 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).

Conclusions

Exo’s AI Platform 2.2 is substantially equivalent in intended use, design, principles of operation, technological characteristics, and safety features to the predicate device. The modification implemented in version 2.2 - an enhancement to the Quality AI module with expanded view support - does not introduce new questions of safety or effectiveness when the device is used as intended.

The performance of the AI Platform 2.2 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 lung and cardiac functionalities did not change during the development of the AI Platform 2.2 product and remain as per the cleared algorithms in K240953.