November 20, 2024

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

Re: K242359
Trade/Device Name: Strain AI (SAI001)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: October 22, 2024
Received: October 22, 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.

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,

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

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)*
K242359

Device Name
Strain AI (SAI001)

Indications for Use *(Describe)*
Strain AI is intended for noninvasive processing of cardiac ultrasound images to provide measurements of global longitudinal strain of adult patients with suspected disease.

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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K242359

510(k) Summary

General Information

510(k) Sponsor	Exo Inc.
Address	4201 Burton Drive Santa Clara, CA 95054
Correspondence Person	Jacqueline Murray
Contact Information	jmurray@exo.inc Cell: +1 236-838-5056
Date Prepared	August 8, 2024

Proposed Device

Proprietary Name	Strain AI (SAI001)
Common Name	Strain AI
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	Us2.v2
Premarket Notification	K233676
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Device Description

Exo's Strain AI is a software as a medical device (SaMD), intended as an aid in diagnostic analysis of echocardiography data. It specifically measures the global longitudinal strain (GLS) from apical 4-chamber (A4C) cardiac ultrasound images.

This software is developed as a module to be integrated by another computer programmer into their legally marketed ultrasound imaging device.

The software does not have a built-in viewer; instead, it integrates into a third-party ultrasound imaging device. The software functions as a post-processing tool, analyzing images after they are acquired. End-users have the option to accept or reject the provided measurements.

Strain AI takes as input image data and provides as an output a quantitative measurement of the global longitudinal strain (GLS) from apical 4-chamber (A4C) cardiac ultrasound images. It is important to note that patient management decisions should not be made solely on the results of the Strain AI analysis.

Indications for Use

> Strain AI is intended for noninvasive processing of cardiac ultrasound images to provide measurements of global longitudinal strain of adult patients with suspected disease.

Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	**Subject Device** Strain AI	**Predicate Device** LVivo Software Application (**K210053**)	**Reference Device** Us2.v2 (**K233676)**
Physical Characteristic	Software package that operates utilizing off-the-shelf hardware	Same as subject device	Same as subject device
Scan type	Multi-frame ultrasound 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

Feature/ Function	**Subject Device** Strain AI	**Predicate Device** LVivo Software Application (**K210053**)	**Reference Device** Us2.v2 (**K233676)**
AI Algorithm	Deep Convolutional Neural Networks for Segmentation or Landmark Detection	Same as Subject Device	Same as subject device
Anatomical Sites	Heart	Heart, Bladder	Same as subject device
GLS calculation	Yes	Same as Subject Device	Same as Subject Device

Performance Data

Safety and performance of the Strain AI 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 Strain AI was successfully evaluated on test data encompassing diverse demographic variables, including gender, age (ranging from 21 to 96), and ethnicity from multiple clinical sites in metropolitan cities with diverse racial patient populations. The Strain function was evaluated with subjects, on images acquired during a routine clinical practice 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 acquired from independent clinical sites and was not used for any part of the training. We established auditability measures, by assigning a unique identification number to each study and its corresponding images.

The ground truth (reference data) was obtained using the reference device. Performance was assessed by calculating the intraclass correlation coefficient (ICC) and root mean square difference (RMSD).

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

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

Measurement	**ICC** (95% CI)	**RMSD** (95% CI)
Global Longitudinal Strain (GLS)	**0.95** (0.91 – 0.97)	**2.76** (2.44 – 3.17)

The device performance was also assessed across a wide range of Ultrasound manufacturers and demographic subgroups (Gender, Image source, Age and BMI). The evaluation concluded that the device performance was consistent among clinically meaningful subgroups.

Conclusions

Exo's Strain AI 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 Strain AI when used as intended.