Exo Inc.
℅ Jacqueline Murray
Senior Regulatory Affairs Specialist
4201 Burton Drive
SANTA CLARA CA 95054

June 22, 2023

Re: K230497
Trade/Device Name: Bladder AI (AIBV01)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: April 18, 2023
Received: May 18, 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 (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,

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.

Submission Number *(if known)*

K230497

Device Name

Bladder AI (AIBV01)

Indications for Use *(Describe)*

Bladder AI uses machine-learning techniques to aid in the quantification of bladder volume from ultrasound images. The device is intended to be used on images of patients aged two years or older.

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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K230497

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: +236 838-5056
Date Prepared	February 23, 2023

Proposed Device

Proprietary Name	Bladder AI(AIBV01)
Common Name	Exo Bladder AI
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Predicate Device

Proprietary Name	MEDO-Thyroid
Premarket Notification	K203502
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Reference Device

Proprietary Name	LVivo Bladder
Premarket Notification	K200232
Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Product Code	QIH
Regulatory Class	II

Device Description

Bladder AI is a standalone software as a medical device (SaMD) that helps qualified users with image-based assessment of bladder ultrasound images in patients aged 2 or older. It is designed to simplify workflow by helping trained healthcare providers evaluate, quantify, and generate reports for bladder ultrasound images.

Bladder AI takes as an input imported Digital Imaging and Communications in Medicine (DICOM) images from ultrasound scanners and allows users to measure bladder volumes of a single frame and multi-frame ultrasound images, as well as create and finalize examination reports. It provides users with a specific toolset for viewing ultrasound images of the bladder, placing landmarks, and creating reports.

Key features of the software are

- ML-based semi-automatic landmark placements
- Bladder dimension and volume measurements
- Report generation

Training and validation datasets have been selected and maintained to be appropriately independent of one another. All potential sources of dependence, including patient and site factors, have been considered and addressed to assure independence.

Indications for Use

Bladder AI uses machine-learning techniques to aid in the quantification of bladder volume from ultrasound images. The device is intended to be used on images of patients aged two years or older.

Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	**Subject Device** Bladder AI (**K230497**)	**Predicate Device** MEDO-Thyroid (**K203502**)	**Reference Device** LVivo Bladder (**K200232**)
Image input	Complies with DICOM Standard	Complies with DICOM Standard	Complies with DICOM Standard

Feature/ Function	**Subject Device** Bladder AI (**K230497**)	**Predicate Device** MEDO-Thyroid (**K203502**)	**Reference Device** LVivo Bladder (**K200232**)
Scan type	Single and Multi-frame images	Single and Multi-frame images	Single-frame images
Image display mode	Static	Static	Static
Image navigation and manipulation tools	Slice-scroll, pane layout, reset	Slice-scroll, pane layout, reset	Slice-scroll, pane layout, reset
Image review	Yes, capable of reviewing all frames of multi-frame (multi-slice) images	Yes, capable of reviewing all frames of multi-frame (multi-slice) images	Yes, capable of reviewing images
Manual landmark placement	Yes	Yes	Yes
Semi-automatic landmark placement	Yes, user-modifiable	Yes, user-modifiable	Yes, user-modifiable
Quantitative analysis	Distance, Volume	Distance, Volume	Distance, Volume
Report creation	Yes	Yes	Yes
Display Calipers	Yes	Yes	Yes
Frame	Transverse and Sagittal Views	Transverse and Sagittal Views	Transverse and Sagittal Views
Operating System	Web browser (Google Chrome)	Web browser (Google Chrome)	Web browser (Google Chrome) and Android
Algorithm	Image segmentation for border detection	Image segmentation for border detection	Image segmentation for border detection

Performance Data

Safety and performance of Bladder AI have 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 Guidance (May 2005), *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and FDA Guidance (June 2022) *"Technical performance assessment of quantitative imaging in radiological device premarket submissions".*

Validation Performance testing

The clinical performance on Bladder AI was successfully evaluated on 122 subjects, on images acquired from cart-based and portable ultrasound devices (with frequency ranging from 1.3 to 9 MHz) and on bladder volumes ranging between 11 to 645 mL.

A diverse collection of clinical sites in metropolitan cities contributed to the test data, encompassing a broad range of demographic variables. These variables included ethnicity, gender, as well as age, spanning from 2 to 95 years old.

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 bladder volume (reference data) was obtained as the average bladder volume measurement among three expert clinicians. Performance was assessed by calculating the intraclass correlation coefficient (ICC) and 2-sided 95% Confidence Interval of the Bladder Volume error. The measurement accuracy and reliability of Bladder AI compared with this reference data is summarized in Table 1.

Table 1: Summary of Bladder AI measurement accuracy and reliability.

	Accuracy	Reliability
	Mean volume difference (Limits of Agreement)	Intraclass correlation coefficient (ICC)
Bladder volume, Dual-View[1]	2 mL (LoA: -42 to 46)	0.98
Bladder volume, Single-View[2]	3 mL (LoA: -49 to 55)	0.97

The results demonstrated that the algorithm performance is reliable and accurate compared to expert clinician. Additionally, the evaluation concluded that the algorithm's performance was consistent among clinically meaningful subgroups: age, gender, BMI and device manufacturers. Overall, the results support the generalizability of the Bladder AI across the intended patient population.

Conclusions

Exo's Bladder 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 Bladder AI when used as intended.

[1] Dual-View bladder volume is calculated from both transverse and sagittal views.
[2] Single-View bladder volume is calculated from only one view.