December 18, 2025

UltraSight Ltd.
Noa Avisar
VP Clinical and Regulatory Affairs
8 Pinhas St.
Ness Ziona, 7403631
Israel

Re: K252235
Trade/Device Name: PVAD IQ Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 14, 2025
Received: November 14, 2025

Dear Noa Avisar:

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.

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)*
K252235

Device Name

PVAD IQ Software

Indications for Use *(Describe)*

The PVAD IQ software is intended for non-invasive analysis of ultrasound images to detect and measure structures from cardiac ultrasound of patients 18 years old and above, with a Percutaneous Ventricular Assist Device (PVAD). Such use is typically utilized for clinical decision support by a qualified physician.

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.

510(k) SUMMARY
UltraSight's PVAD IQ Software

Applicant name: UltraSight Ltd.
Applicant address:
8 Pinhas Sapir St. Ness Ziona 7403631, Israel
Phone: +972-54-8886425
Email: noa@ultrasight.com
Contact Person: Noa Avisar
Date: November 14, 2025

Name of Device: PVAD IQ Software
Classification Name: Medical image management and processing system
Classification Code: QIH
Device class: II
Regulation number: 892.2050
Panel: Radiology
Predicate Device: LVivo Software Application (K210053)

Intended Use/ Indications for Use

The PVAD IQ Software is intended for non-invasive analysis of ultrasound images to detect and measure structures from cardiac ultrasound of patients 18 years old and above, with Percutaneous Ventricular Assist Devices (PVAD). Such use is typically utilized for clinical decision support by a qualified physician.

Device Description

PVAD IQ is a Software as a Medical Device (SaMD) solution designed to support clinicians in the positioning of Percutaneous Ventricular Assist devices (PVADs) through ultrasound image-based assessment. Percutaneous Ventricular Assist device is a temporary device used to provide hemodynamic support for patients experiencing cardiogenic shock or undergoing high-risk percutaneous coronary interventions (PCI).

The PVAD IQ software is a machine learning model (MLM) based software, that operates on ultrasound clips (as the system input) and provides two outputs with regards to PVAD patients:

1. Landmark identification and measurement - provides the two landmarks position detection, and computation of the mean distance between the two landmarks- the aortic annulus and the PVAD inlet.

2. Acceptability classification, which is a binary classification of ultrasound clips that are "acceptable" or "non-acceptable", in terms of visibility of the two landmarks. A clip is defined as acceptable when both landmarks are simultaneously visible in a manner suitable for quantitative imaging.

The User Interface (UI) enables the user to review or hide the mean distance measurement, annotate desired images, and add manual measurement, while keeping the raw data for further review as needed.

The software output is shown on the screen either as the mean distance measurement, or as a notification related to non-acceptable clips.

Technological Characteristics

PVAD IQ software is an ultrasound image processing software implementing non-adaptive machine learning algorithms trained with clinical data and intended for automated analysis of transthoracic echocardiography (TTE) using ultrasound clips.

Substantial Equivalence Discussion

The PVAD IQ software and the predicate device have the same intended use and similar indications, technological characteristics and principles of operation; both devices process TTE ultrasound clips to support clinical management of cardiac patients using machine learning technology.

Though the subject device provides different measurements output, compared to the predicate, these differences do not raise new questions of safety and effectiveness. The subject device has been demonstrated to be as safe and effective as the predicate device and is therefore considered substantially equivalent.

A table comparing the key features of the subject and the predicate devices is provided below:

Feature	**PVAD IQ Software (Subject device)**	**LVivo Software Application (Predicate device) K210053**	**Conclusion**
Classification Name	Medical image management and processing system	Same	Identical
Regulation Name	21 CFR 892.2050	Same	
Product code	QIH	Same	
Device Class	II	Same	

Intended Use	Non-invasive processing of ultrasound images	Same	Identical
Indications for use	The PVAD IQ device is intended for non-invasive analysis of ultrasound images to detect and measure structures from cardiac ultrasound of patients 18 years old and above with Percutaneous Ventricular Assist Devices (PVAD). Such use typically utilized for clinical decision support by a qualified physician.	LVivo platform is intended for non-invasive processing of ultrasound images to detect, measure, and calculate relevant medical parameters of structures and function of patients with suspected disease	Similar
Scan type	Ultrasound (ultrasound vendor neutral)	Same	Identical
Principle of Operation and Technology	Ultrasound image processing software implementing non-adaptive machine learning algorithms trained with clinical data intended for non-invasive analysis of ultrasound data	Same	Identical
Algorithm	Deep Convolutional Neural Networks for Landmark Detection and Classification	Same	Identical
Anatomical site	Heart	Same	Identical

Main Output	Clinically relevant measurements of known structure for management support in cardiac patients. Measurement: Distance between the aortic annulus and the PVAD inlet	Clinically relevant measurements of known structure for management support in cardiac patients. Measurement: Left ventricular ejection fraction (LVEF), global Longitudinal Strain Measure, Segmental Longitudinal Strain Measure, and Segmental wall motion evaluation	Similar output with different measurements

Table 1: Substantial Equivalence

Non-Clinical Performance Data

The PVAD IQ software focuses on quantifying the distance between the Aortic Annulus and the PVAD inlet (e.g., Impella®), a critical metric for confirming PVAD device positioning in the heart. This function supports clinical decision-making by providing automated analysis of TTE clips.

To establish performance, PVAD IQ software was evaluated using geographically distinct test datasets comprising 963 clips from 186 patients.

Ground truth annotations for the distance between the aortic annulus and the PVAD inlet were provided by US (United States) board certified cardiac sonographers experienced in PVAD/Impella® echocardiographic imaging. The performance criteria were defined as:

1. Distance measurement: a mean absolute error (MAE) with a 95% confidence interval (CI) upper bound below 0.5 cm. The PVAD IQ software achieved an MAE of 0.42 cm with a 95% CI of (0.38–0.47 cm)
2. Acceptability classification requirement: Cohens kappa above 0.6. result: 0.71 with a 95% CI of (0.66–0.75)
3. Landmark detection of inlet and aortic annulus requirement: AUC above 0.8. result: Inlet: 0.92 (0.9-0.94). Annulus: 0.98 (0.95, 1)
4. Landmark position requirement: MAE below 0.5 cm. results: Inlet: 0.44 (0.41-0.48) Annulus: 0.31 (0.3, 0.33)

PVAD IQ meets the pre-specified acceptance criteria for clinical safety and accuracy. The model showed consistent performance across the entire operating range with no observed systematic bias, supporting its use in clinical workflows for PVAD position verification.

Software and Cybersecurity*:*
The device underwent comprehensive software validation and cybersecurity testing in accordance with the FDA's Guidance "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". These validations ensured the software meets its intended use, functions reliably under the expected conditions and incorporates appropriate risk-based cybersecurity controls. The submission includes documentation of threat modeling, vulnerability testing, and secure design practices to support substantial equivalence of the device in today's evolving cybersecurity landscape.

Predetermined Change Control Plan (PCCP)

This submission includes a Predetermined Change Control Plan (PCCP) detailing the proposed device modifications. The PCCP outlines the nature of these planned changes and provides a modification protocol to guide the testing, verification, validation, and implementation processes, ensuring the device continues to meet substantial equivalence.
The planned modifications described in the PCCP are summarized in the table below. In alignment with the PCCP, the updated PVAD IQ software will undergo appropriate training, tuning, testing, and finalization before being released with the retrained model. Users will be informed of these changes through software update notifications and revised labeling.
Table 2 below describes each of the proposed modifications and describes how it will be tested to ensure substantial equivalence of the device after the modification.

Modification	Description	Testing Method
Re-training	Model retraining for enhanced output accuracy and MLM performance, refining annotations, and bounded architecture optimization, to enhance robustness, generalizability, and performance, as part of the device life cycle management. No changes to device input or output	Verification testing will assess non-clinical performance using the established acceptance criteria. The evaluation includes distance measurement between the aortic annulus and the PVAD inlet, clip acceptability classification, inlet and aortic-annulus visibility, and inlet and aortic-annulus landmark position. These metrics will be tested using the same methods and thresholds defined

		for the authorized device to confirm that retraining maintains performance within the validated boundaries. Software testing: Per FDA's Guidance "Content of Premarket Submissions for Device Software Function" Cybersecurity testing: Per FDA's Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".
Additional PVAD Devices	MLM will include datasets with Percutaneous Ventricular Assist Devices, that were not previously tested with the authorized device, in order to expand the use of the PVAD IQ software. The additional PVAD devices should be FDA approved, indicated to support the left ventricle, and within the device patient population.	Verification testing will assess non-clinical performance using the established acceptance criteria. The evaluation includes distance measurement between the aortic annulus and the PVAD inlet, clip acceptability classification, inlet and aortic-annulus visibility, and inlet and aortic-annulus landmark position. These metrics will confirm that adding new PVAD devices maintains performance within the established boundaries. Software testing: Per FDA's Guidance "Content of Premarket Submissions for Device Software Function" Cybersecurity testing: Per FDA's Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".
Additional Ultrasound Views	MLM will include datasets from other cardiac ultrasound views (AP3, AP5, and Subcostal LVOT), allowing healthcare	Verification testing will assess non-clinical performance using the established acceptance criteria. The evaluation includes distance

	professionals to use the software with different views as needed.	measurement between the aortic annulus and the PVAD inlet, clip acceptability classification, inlet and aortic-annulus visibility, and inlet and aortic-annulus landmark position. These evaluations will be applied to clips containing the new ultrasound views to confirm that model performance remains within the validated limits Software testing: Per FDA's Guidance "Content of Premarket Submissions for Device Software Function" Cybersecurity testing: Per FDA's Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Table 2: PCCP Modifications

Conclusion

In this Traditional 510(k) premarket notification, UltraSight Ltd. demonstrates that the proposed PVAD IQ software is substantially equivalent to the predicate device, sharing the same intended use, and similar indications, technological characteristics, and principles of operation.

A Predetermined Change Control Plan (PCCP) is included to outline post-clearance modifications and their evaluation. Each planned change includes an impact assessment and test plan to ensure continued safety, effectiveness, and substantial equivalence to the predicate device.