December 17, 2025

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

Re: K251416
    Trade/Device Name: UltraSight Guidance
    Regulation Number: 21 CFR 892.2100
    Regulation Name: Radiological Acquisition And/Or Optimization Guidance System
    Regulatory Class: Class II
    Product Code: QJU
    Dated: November 19, 2025
    Received: November 19, 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
    Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*

K251416

Device Name

UltraSight Guidance

Indications for Use *(Describe)*

The UltraSight Guidance is intended to assist medical professionals (not including expert sonographers) in acquiring cardiac ultrasound images. UltraSight Guidance is an accessory to compatible general-purpose diagnostic ultrasound systems. UltraSight Guidance is indicated for use in two-dimensional transthoracic echocardiography (2D- TTE) for adult patients, specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).

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 Guidance

K251416

Applicant name: UltraSight Ltd.

8 Pinhas Sapir St.
Ness Ziona 7403631
Israel
Phone: +972-54-8886425
Email: noa@ultrasight.com
Contact Person: Noa Avisar
Date Prepared: 11/11/2025

Name of Device: UltraSight Guidance

Classification Name: Image Acquisition And/Or Optimization Guided By Artificial Intelligence

Classification Code: QJU

Device class: II

Regulation number: 892.2100

Panel: Radiology

Predicate Devices: UltraSight Guidance Software (K223347)

Intended Use / Indications for Use

The UltraSight Guidance is intended to assist medical professionals (not including expert sonographers) in acquiring cardiac ultrasound images. UltraSight Guidance is an accessory to compatible general-purpose diagnostic ultrasound systems. UltraSight Guidance is indicated for use in two-dimensional transthoracic echocardiography (2D- TTE) for adult patients, specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).

Device Description

UltraSight Guidance is a software application based on machine learning that uses artificial intelligence (AI) to provide dynamic real-time guidance on the position and orientation of the transducer to help non-expert users acquire diagnostic-quality tomographic views of the heart. The system provides guidance for ten standard cardiac views.

Main features:

- Quality Bar: The system displays an image quality bar that is continuously updated while the user scans the subject, while attempting to find the maximal quality. The quality bar is a score for image diagnosability. It represents the classification between high and low quality images, where high quality images are defined as grade 3 or more based on American College of Emergency Physicians (ACEP) guidelines (Rachel B. Liu et al., "Emergency Ultrasound Standard Reporting Guidelines", 2018, American College of Emergency Physicians)

- Probe Guidance: The probe guidance feature provides graphic on-screen instructions for the user to emulate how a sonographer would manipulate the transducer to acquire the target cardiac view. The five possible guidance cues are rotation, tilt, rock, and slides in the lateral-medial and up/down directions (with respect to the subjects' head).

  The guidance user interface (UI) is composed of a 3D probe display that shows orientation guidance cues (rotations, tilts and rocks) and a cross that shows slide guidance cues (slides in x and y directions). The users infer the maneuver they should perform from viewing the 3D probe display and the slides cross. Supporting text messages appear on the screen regarding guidance cues.

This device is a modification of a previously marketed device, where the main modification introduced is the addition of a pre-processing step, done prior to feeding images as an input to the device. This modification is aimed to enable future compatibility with potentially additional ultrasound probes that meet pre-requisites (as part of a pre-determined change control plan).

Technological Characteristics

The UltraSight Guidance software application is similar in its technological features to its predicate device. Both systems are intended as an assistive tool to aid medical professionals in the acquisition of cardiac ultrasound images. Specifically, both systems are indicated to aid in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).

The technological characteristics of the UltraSight Guidance software are identical to the technological characteristics of the predicate device. Both systems apply MLM based algorithms to provide real-time guidance on how to position and manipulate the transducer on a patient's body. Both systems are coupled with a third-party, previously cleared ultrasound system and provide to the users real-time guidance during acquisition of 2D echocardiography to assist them in obtaining echocardiography images that represent standard diagnostic views and orientations.

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

Table 1: Substantial Equivalence

Parameters	UltraSight AI Guidance (K223347)	Proposed UltraSight Guidance (K251416)	Conclusion
Classification name	Image Acquisition And/or Optimization Guided by Artificial Intelligence	Same	Identical
Product Code	QJU	Same	Identical
Intended Use	The UltraSight AI Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. UltraSight AI Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems	Same	Identical
Indications for use	The UltraSight AI Guidance is intended to assist medical professionals (not including expert sonographers) in acquiring cardiac ultrasound images. UltraSight AI Guidance is an accessory to compatible general-purpose diagnostic ultrasound systems. UltraSight AI Guidance is indicated for use in two-dimensional transthoracic echocardiography (2D- TTE) for adult patients, specifically in the acquisition of the following standard views: Parasternal Long-Axis (PLAX), Parasternal Short-Axis at the Aortic Valve (PSAX-AV), Parasternal Short-Axis at the Mitral Valve (PSAX-MV), Parasternal Short-Axis at the Papillary Muscle (PSAX-PM), Apical 4-Chamber (AP4), Apical 5-Chamber (AP5), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3),	Same	Identical

Parameters	UltraSight AI Guidance (K223347)	Proposed UltraSight Guidance (K251416)	Conclusion
	Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).		
Intended user	Medical professionals (not including expert sonographers)	Same	Identical
Compatible Ultrasound system and probe	Philips Lumify with S4-1 probe and compatible tablets defined in the labeling	Same	Identical
Clinical Features:			
Image acquisition guidance	Probe Guidance: this feature, which is the core of the application, provides on-screen instructions to the user to emulate how an expert would manipulate the transducer to acquire the optimal view.	Same	Identical
Real time feedback on image quality	Quality bar: real-time feedback on the clip's quality advises the user on the expected diagnostic quality of the current clip. This information can be used by the users to assess how close they are to capturing a diagnostic-quality image.	Same	Identical
Deep Learning Based Algorithm	Downloadable application that utilizes artificial intelligence (AI) to provide real-time dynamic guidance of transducer position and orientation to help non-expert users acquire diagnostic-quality tomographic views of the heart.	Same	Identical

Parameters	UltraSight AI Guidance (K223347)	Proposed UltraSight Guidance (K251416)
Predetermined Change Control Plan (PCCP): M1 Retraining - to enhance MLM performance, to optimize MLM performance for specific demographic population within the intended use, and to increase stability in consecutive MLM predictions.	Not included	Added to the PCCP
M2 Expand compatibility with additional ultrasound systems	Not included	Added to the PCCP
M3 Addition of target cardiac views	Not included	Added to the PCCP

Substantial Equivalence

The UltraSight Guidance software has the same intended use, indications for use, technological characteristics and principles of operation as the predicate device. As discussed above, while there are minor differences between the subject and predicate devices, the differences do not raise any different questions of safety or effectiveness, and bench performance data is available to demonstrate that the performance of UltraSight Guidance is equivalent to the performance of the predicate device. Therefore, the devices are substantially equivalent.

Non-Clinical Performance Data

The following performance testing was conducted to evaluate the device:

Quality Bar:

The quality bar is a score for image diagnosability. It represents the classification between high- and low-quality images, where high quality images are defined as grade 3 or more based on ACEP guidelines.

The test dataset was collected from clinical sites geographically distinct from those used for the development dataset. It included a total of 134 patients - 111 from the USA and 23 from Israel - comprising 26,362 ultrasound clips. The dataset represents a diverse patient population with variations in body mass index (BMI: 18-39.3), age (18 - 91 years), and sex (50.7% female and 49.3% male).

Each clip in the dataset is associated with a target cardiac view and was annotated with a clip diagnosability label (diagnosable / non-diagnosable).
The test assessed the classification performance between "diagnosable" and "non diagnosable" clips of each view. The clips were annotated by two expert cardiologists for its diagnosability. In case of disagreement, a third cardiologist provided additional annotation, and the final label was determined

by majority vote among the three experts. The mean area under the receiver operating characteristic curve (AUC) was within the pre-defined acceptance criteria (AUC > 0.8) with 95% CI showing good classification performance, relative to the success criteria. The mean false positive rate (FPR) met the acceptance criteria of FPR <0.2 with 95% CI showing good classification performance. Subgroup analyses were conducted across BMI categories (<25, ⩾25 and <30, ⩾30), age groups (< 50, ⩾50 and <65, ⩾65), sex (male and female) and US vs non-US.

Probe Guidance:

The system provides guidance cues when the heart is visible on the ultrasound image. To provide the correct guidance cues, the system needs to be able to identify the position and orientation of the probe relative to the target cardiac view. There are five possible guidance cues: rotations, tilts, rocks, and slides in the x (lateral-medial) and y (superior-inferior) directions.

The test dataset was collected from clinical sites geographically distinct from those used for the development dataset. It included a total of 134 patients - 111 from the USA and 23 from Israel - comprising 2.4 million ultrasound frames. The dataset encompasses a diverse patient population with variation in body mass index (BMI: 18-39.3), age (18 - 91 years), and sex (50.7% female and 49.3% male).

Ground truth was established by expert sonographers and/or cardiologists using the recorded probe position during ultrasound acquisition. The relative position of the probe at each frame, compared to the position associated with the target view, defined the required rotation, tilt, rock and slides adjustments.

The testing evaluated the frame level accuracy of each guidance cue prediction. For each guidance cue, a series of tests was defined to check if the guidance cue is functioning correctly in a particular direction (for example, clockwise rotations relative to 2C view, tilts up from PLAX). Each test was formulated as a binary classification test. The mean AUC was within the acceptance criteria of AUC>0.8 with 95% CI showing good classification performance. Subgroup analyses were conducted across BMI categories (<25, ⩾25 and <30, ⩾30), age groups (< 50, ⩾50 and <65, ⩾65), sex (male and female) and US vs non-US.

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 evaluations ensured the software meets its intended use, functions reliably under expected conditions, and incorporates appropriate risk-based cybersecurity controls. The submission includes documentation of threat modeling, vulnerability testing, and secure design practices to support the safety and effectiveness of the device in today's evolving cybersecurity landscape.

Predetermined Change Control Plan (PCCP)

A Predetermined Change Control Plan (PCCP) is added to describe what modifications will be made to the subject device following the marketing authorization (i.e. 510(k) clearance) and how the modifications will be assessed.

Each modification is provided with an impact assessment and a detailed test plan to ensure the device with a modification maintains safety and effectiveness as the predicate device. The device with the planned modifications has the same intended use, indication for use, technological characteristics and principles of operation as the predicate device, therefore remaining substantially equivalent to the predicate device.

Table 3: PCCP Modifications

Modification	Rationale for Modification	Testing Methods, Validation activities and performance requirements	Communication to users
Model re-training	Improvement and optimization of MLM: Enhance MLM performance, Optimize MLM performance for specific demographic population within the intended use, Increase stability in consecutive MLM predictions.	Repeating verification tests and the system level validation tests to ensure the following pre-defined acceptance criteria are met: Quality Bar: • Mean area under the ROC curve (AUC) > 0.8 • Mean false positive rate (FPR) at the green quality threshold < 0.2 Guidance: • Lower bound of the 95% CI of the mean AUC > 0.8	The labeling will be updated in accordance with the authorized PCCP, to provide users with current information regarding updated performance results.
Expand Compatibility with additional ultrasound systems	Increase accessibility of UltraSight Guidance	Image parameters from the calibrated candidate ultrasound device are compared to the predefined boundaries of applicability. Compatibility is confirmed when the parameters fall within these boundaries.	The labeling will be updated in accordance with the authorized PCCP, with the newly added compatible ultrasound systems. In addition, the user manual will include information on the methodology of how a candidate ultrasound device was approved.
Expanded list of cardiac views	Enhance the system's clinical use by offering guidance to additional supported cardiac views	Repeating verification tests and the system level validation tests to ensure the following pre-defined acceptance criteria are met for both the complete dataset (including enrichment with	The labeling will be updated in accordance with the authorized PCCP, to provide users with current information regarding updated cardiac views to support the change.

| | | additional supported views) and the original test dataset: Quality Bar: • Mean area under the ROC curve (AUC) > 0.8 • Mean false positive rate (FPR) at the green quality threshold < 0.2 Guidance: • Lower bound of the 95% CI of the mean AUC > 0.8 Clinical utility test will evaluate the ability of non-expert users to obtain diagnostic-quality cardiac images using UltraSight software for the newly added cardiac views. Images will be evaluated by experts for a pre-defined clinical outcome related to the view and for their diagnostic-quality. The study will be considered successful when the clinical outcome can be achieved in ≥75% of subjects. | |

Conclusions

In this Traditional 510(k) premarket notification, UltraSight Ltd. demonstrates substantial equivalence of the proposed UltraSight Guidance software to the currently marketed and predicate device UltraSight AI Guidance (K223347). UltraSight Guidance Software has the same intended use and indications for use, and same technological characteristics, and principles of operation as the predicate device. The modifications implemented in the subject device do not raise different questions of safety or effectiveness.