July 24, 2023

UltraSight Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
PHILADELPHIA PA 19103

Re: K223347
Trade/Device Name: UltraSight AI Guidance
Regulation Number: 21 CFR 892.2100
Regulation Name: Radiological acquisition and/or optimization guidance system
Regulatory Class: Class II
Product Code: QJU
Dated: June 23, 2023
Received: June 23, 2023

Dear Janice Hogan:

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,

Yanna S. Kang -S

Yanna Kang, Ph.D.
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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)*

K223347

Device Name
UltraSight AI Guidance

Indications for Use *(Describe)*

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), 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)

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510(k) SUMMARY
UltraSight's UltraSight AI Guidance K223347

Applicant name: UltraSight Ltd.

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Email: info@ultrasight.com
Contact Person: Davidi Vortman
Date Prepared: July 19, 2023

Name of Device: UltraSight AI 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: Caption Health's Caption Guidance (DEN190040)

Intended Use / 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), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).

Device Description

UltraSight AI Guidance is a mobile 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 ACEP guidelines (Rachel B. Liu et al., "Emergency Ultrasound Standard Reporting Guidelines", 2018, American College of Emergency Physicians).
- View Detection: The system differentiates between three states, and the display adjusts accordingly:
    1. No heart - heart is not visible, the user is expected to first find the acoustic window where some heart tissue is visible and then follow the navigation instructions.
    2. Navigate - the quality bar is below 8 bars, the heart is visible, the user should watch the guidance cues and move the probe accordingly.
    3. Hold position - the quality bar has reached 8 bars (or more), the tail of the probe turns green, and the user should record a clip. Saving a clip functionality is not part of the UltraSight AI system; the user saves the clip manually using the Lumify interface.
- 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, rotation, tilt, rock, and slides in the lateral-medial and up/down (with respect to the subjects' head) directions.

  The guidance user interface 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 user infers the maneuver they should perform from viewing the 3D probe display and the slides cross. No explicit text messages appear on the screen regarding guidance cues.

Technological Characteristics

The UltraSight AI Guidance software application is similar in its technological features to its predicate device, the Caption Health's Caption Guidance (DEN190040). 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). Both systems are software applications that apply deep learning-based algorithm to emulate the expertise of a sonographer by providing real-time guidance on how to position and manipulate the transducer on a patient's body. Both systems are installed on a third-party, previously cleared ultrasound device. There are minor technological differences between the subject and the predicate device, mainly the ultrasound device with which the software interfaces and few features offered by the predicate device and not by the subject device (auto capture and save best clip). However, as explained in more detail

below, these differences do not raise new or different questions of safety or effectiveness since the principal technology remains very similar and, in both instances, the key question is whether the device enables the intended users to acquire limited (10-view) 2D transthoracic echocardiography (2D-TTE) in diagnostic quality. The clinical and human factors validation demonstrated that the use of the UltraSight AI Guidance, by users with no prior scanning experience, enabled users to acquire limited (10-view) 2D transthoracic echocardiography (2D-TTE) with similar performance as the predicate device.

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

Parameters	**Caption Guidance DEN190040**	**Proposed UltraSight AI Guidance**	**Conclusion**
Classification name	Image Acquisition And/ Or Optimization Guided By Artificial Intelligence	Image Acquisition And/ Or Optimization Guided By Artificial Intelligence	Identical
Product Code	QJU	QJU	Identical
Intended Use	The Caption Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. Caption Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems	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	Identical
Indications for use	Caption Guidance software 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),	UltraSight AI Guidance software 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),	Similar Since the use of the UltraSight AI Guidance and its impact to expert sonographers has not been evaluated, this users' population is excluded from the device's intended users.

Parameters	Caption Guidance DEN190040	Proposed UltraSight AI Guidance	Conclusion
	Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).	Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC). The UltraSight AI Guidance is not intended to be used by Sonographers.	
Intended user	Medical professionals (including expert sonographers)	Medical professionals (not including expert sonographers)	Substantially Equivalent: It should be noted that the intended users' population of the UltraSight AI Guidance is slightly narrower than the predicate and does not include sonographers. However, the intended user population of the UltraSight AI Guidance is a subset of the broader user population for the predicate; thus, the intended use and indications are fully encompassed within the predicate indications. Therefore, the first criterion for a finding of substantial equivalence is satisfied.
Compatible Ultrasound system and probe	The uSmart 3200t Plus ultrasound system with the 3200t-compatible Terason 4V2A linear phased array probe	Philips Lumify With S4-1 probe and Samsung Tab S6 and S7 tablets	Substantially Equivalent: Both the predicate device and the proposed device function as a software accessory to a cleared to market ultrasound device. Both ultrasound devices are cleared for the diagnostic ultrasound clinical application of acquiring cardiac images

Parameters	Caption Guidance DEN190040	Proposed UltraSight AI Guidance	Conclusion
			of adult patients. Since both ultrasound devices are cleared for the required clinical use, the use of different ultrasound devices does not raise new questions of safety and/or effectiveness.
Clinical Features			
Image acquisition guidance	Prescriptive Guidance: The prescriptive guidance feature in Caption Guidance provides direction to the user to emulate how a sonographer would manipulate the transducer to acquire the optimal view	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.	Substantially Equivalent: While the user interface is slightly different, the functionality and type of guidance provided to the user will be the same. Specifically, both devices provide to the user instructions on how to manipulate the probe (translational, tilt and rotation guidance cues) together with real-time feedback on the expected diagnostic quality of the resulting clip to direct the user to a probe position that will enable acquisition of a diagnostic quality clip. Hence, this difference does not raise new questions of safety and/or effectiveness.
Real time feedback on image quality	Quality Meter: a real-time feedback from the Quality Meter advises the user on the expected diagnostic quality of the resulting clip, such that the user can make decisions to further optimize the quality, for example by following the prescriptive guidance feature below.	Quality Bar: a real-time quality bar providing feedback on the clip's quality advises the user on the expected diagnostic quality of the current image. This information can be used by the users to assess how close they are to capturing a diagnostic-quality image.	Substantially Equivalent

Parameters	Caption Guidance DEN190040	Proposed UltraSight AI Guidance	Conclusion
Automatic capture of clips with predicted diagnostic quality	Auto-Capture: The Caption Guidance Auto-Capture feature triggers an automatic capture of a clip when the quality is predicted to be diagnostic, emulating the way in which a sonographer knows when an image is of sufficient quality to be diagnostic and records it.	None	Substantially Equivalent: This feature is not provided; the UltraSight software provides to the user the view detection and quality bar features which enable any user to clearly identify when a diagnostic quality image has been achieved and to manually save the clip.
Retrospectively recording of highest quality clip	Save Best Clip: This feature continually assesses clip quality while the user is scanning and, in the event that the user is not able to obtain a clip sufficient for Auto-Capture, the software allows the user to retrospectively record the highest quality clip obtained so far, mimicking the choice a sonographer might make when recording an exam.	None	Substantially Equivalent: Although this feature is not provided, the UltraSight software provides to the user the view detection and quality bar features which enable any user to clearly identify when a diagnostic quality has been achieved and to manually save the clip.
Deep Learning Based Algorithm	Yes	Yes	Substantially Equivalent

Substantial Equivalence

The UltraSight AI Guidance is as safe and effective as the Caption Health's Caption Guidance. The UltraSight AI Guidance has the same intended uses and indications for use and similar technological characteristics, and principles of operation as its predicate device. The minor technological differences between the UltraSight AI Guidance and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the UltraSight AI Guidance is as safe and effective as Caption Health's Caption Guidance. Thus, UltraSight AI Guidance is substantially equivalent to Caption Health's Caption Guidance.

Non-Clinical Performance Data

The following testing was conducted to evaluate the device:

1. Software moderate level of concern verification and validation testing was conducted as required by IEC 62304 and FDA Guidance on General Principles of Software Validation, January 11, 2002.

2. UltraSight AI Guidance Algorithms' standalone performance was validated with a number of standalone performance tests, see detailed description below.

3. Human factors Validation: the system was validated with intended users in simulated use conditions to ensure the user needs and intended use requirements were met. All tasks, including a critical task, were met and no new issues of safety or effectiveness were raised.

Non-Clinical Standalone Performance Testing of AI algorithms

The Datasets used for algorithm development and performance testing are listed in **Table 1**:

Table 1: Data used for Algorithm Development and Performance Testing

Phase	Algorithm development	Performance tests for Quality Bar	Performance test for View Detection and Guidance tests
Number of subjects	580	312	75
Number of samples	5 million frames of ultrasound images	5,800 clips	2.3 million frames of ultrasound images

The data used for performance testing was collected at different sites, geographically separated, from the sites used for collection of the algorithm development data. The data used in the performance testing was collected from a population representative to the intended population.

Performance Tests Overview

The following features of the system were tested:

- Quality bar
- View detection (part of the quality bar functionality as explained below)
- Probe Guidance

Each feature of the system (Quality Bar, View Detection, Probe Guidance) was tested independently.

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 was performed on 312 clips. Each clip in the dataset is associated with a target cardiac view and was annotated with a clip diagnosability label (diagnosable / non-diagnosable), by three cardiologists.

The test assessed the classification performance between “diagnosable” and “non diagnosable” clips of each view. The mean AUC was 0.86 with 95% CI [0.85, 0.87] showing good classification performance, relative to the success criteria of AUC > 0.8. The mean PPV was 0.93 with 95% CI [0.92, 0.94] relative to the success criteria of PPV > 0.75, showing good classification performance. Stratified analysis was performed, for each target cardiac view the AUC was greater than 0.8, and the PPV was above 0.75.

View Detection:

The system provides view detection classification that distinguishes between three system states: “Hold Position", “Navigate", and “No Heart". The test was performed on 75 subjects on a total of 2.3 million frames of ultrasound images.

The view detection classification performance is quantified for the classification tasks of “Hold position" vs. “Navigate" and “Hold position" vs. “No heart". The ground truth labels were defined on the frame level using annotation of expert sonographers. The mean AUC was 0.988 with 95% CI [0.985, 0.990] showing good classification performance, relative to the success criteria of AUC > 0.8. Stratified analysis was performed and showed that for each individual binary classification test the AUC was above 0.8.

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 testing was performed on 75 subjects on a total of 2.3 million frames of ultrasound images. 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 0.821 with 95% CI [0.813, 0.827] showing good classification performance, relative to the success criteria of AUC > 0.8. Stratified tests show that individual classifiers have reasonable discrimination ability, and acceptable classifiers.

Human factors Validation:

The UltraSight AI Guide application underwent summative usability validation in accordance with the FDA Guidance Document, "Applying Human Factors and Usability Engineering to Medical Devices" (2016). All user tasks associated with the device were evaluated and critical tasks were identified for usability evaluation, where if performed incorrectly or not performed at all would or could cause serious harm. All participants successfully completed the testing sessions and performed the critical task identified in the study without any use errors, close calls, or other issues.

Based on the results of the summative usability validation, it can be concluded that the UltraSight AI Guide application is deemed adequately safe and effective for its intended users, uses, and use environments.

Clinical Performance Data

Pilot Study

A prospective single center, multi-reader multi-case (MRMC) study, primarily designed to obtain the quality of the clips obtained by medical professionals without specialized echocardiography training (non-expert users) when using the Ultrasound AI was conducted. Sixty-one (61) subjects were scanned twice, once by a non-expert user, using Philips Lumify with the UltraSight AI guidance; and, by a cardiac sonographer using the Philips Lumify hardware but without AI guidance. The clips acquired during those scans were reviewed by a panel of 5 expert cardiologists blinded to whether the clip was acquired by a non-expert user or a sonographer and to each other's evaluations. The cardiologists assessed whether the non-expert users' scans were of sufficient quality for the expert readers to make qualitative visual assessment of left ventricular (LV) size, LV function, right ventricular (RV) size, and the presence of nontrivial pericardial effusion. Six additional echocardiographic parameters were visually assessed as secondary endpoints: qualitative assessment of RV function; left atrium size; structural assessment of the aortic, mitral, and tricuspid valves; and qualitative assessment of IVC size.

The exams performed by the non-expert users had sufficient visual quality in 100% of cases based on majority agreement to assess LV size and function, RV size, and pericardial effusion. For the secondary endpoints, the exams performed by non-expert users had sufficient visual quality based on majority in 90-100% of cases to assess RV function, left atrium size, AV structure, MV structure, TV structure, and IVC size. Furthermore, the exams performed by non-expert users had sufficient diagnostic quality based on majority in 80% to 100% of cases to assess PLAX, PSAX AV, PSAX MV, PSAX PM, AP2, AP3, AP5, Sub4C and SC-IVC. In addition, most clips (range 78.6-97.9%) taken by the non-expert users had a diagnostic quality score of 3 of higher based on American College of Emergency Physicians (ACEP) scale.

Pivotal Study

A prospective multi center, multi-reader multi-case (MRMC) pivotal clinical study was conducted to evaluate the use of UltraSight AI Guidance by medical professionals without specialized echocardiography training (non-expert/novice users).

A total of 240 subjects were scanned twice, once by a non-expert user, using the Philips Lumify with the UltraSight AI guidance; and, by a cardiac sonographer using the Philips Lumify hardware but without AI guidance. The clips acquired during the scans were reviewed by a panel of 5 expert cardiologists blinded to whether the clip was acquired by a non-expert user or a sonographer and to each other's evaluations. The cardiologists assessed whether the non-expert users' scans were of sufficient quality for the expert readers to make qualitative visual assessment of left ventricular (LV) size, LV function, right ventricular (RV) size, and the presence of nontrivial pericardial effusion. Six additional echocardiographic parameters were visually assessed as secondary endpoints: qualitative assessment of RV function; left atrium size; structural assessment of the aortic, mitral, and tricuspid valves; and qualitative assessment of IVC size. For the 4 co-primary endpoints, the non-expert users' scans were judged to have adequate visual quality on the majority agreement to assess the clinical parameters in nearly all subjects, in 93-100% of cases. For the secondary endpoints, the percentage of exams performed by non-expert users that had sufficient visual quality based on majority agreement was 98% for MV structure, 94% for RV function and left atrium size, 89% for AV structure, 74% for TV structure, and 67% for IVC size. Assessment of intra-cardiologists' variability using Cohen's kappa coefficient (κ) was assessed on a randomly selected 10% of the examinations on which a repeated assessment was performed. There was very good agreement among the cardiologists when assessing the primary endpoints. The results of the study showed that exams performed by non-expert users using the UltraSight AI Guidance Software can provide clips with sufficient diagnostic quality even immediately upon completion of training.

Conclusions

The UltraSight AI Guidance is substantially equivalent to Caption Health's Caption Guidance. The UltraSight AI Guidance has the same intended use and indications for use and similar technological characteristics, and principles of operation as its predicate device. The minor technological differences between the UltraSight AI Guidance and its predicate device raise no new issues of safety or effectiveness. Non-clinical and clinical performance data demonstrate that the UltraSight AI Guidance performs as expected and in a manner that is substantially equivalent to its predicate device. Thus, the UltraSight AI Guidance is substantially equivalent.