



April 4, 2025

DESKi
Saray Ugidos Seman
Quality and Regulatory Manager
2 Place de la Bourse
Bordeaux, 33000
FRANCE

Re: K242807
Trade/Device Name: HeartFocus (V.1.1.1)
Regulation Number: 21 CFR 892.2100
Regulation Name: Radiological Acquisition And/Or Optimization Guidance System
Regulatory Class: Class II
Product Code: QJU
Dated: February 28, 2025
Received: March 3, 2025

Dear Saray Ugidos Seman:

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.
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Enclosure

Indications for Use

510(k) Number (if known)
K242807

Device Name
HeartFocus (V.1.1.1)

Indications for Use (Describe)

The HeartFocus software is intended to assist and guide medical professionals in the acquisition of cardiac ultrasound images. HeartFocus software is an accessory to compatible general-purpose diagnostic ultrasound systems. Heartfocus guides the acquisition of two-dimensional transthoracic echocardiography (2D-TTE). 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 (A4C), Apical 5-Chamber (A5C), Apical 2-Chamber (A2C), Apical 3-Chamber (A3C), Subcostal 4-Chamber (SC-4C), and Subcostal inferior Vena Cava (SC-IVC).

HeartFocus software is indicated for use in adult patients who require a cardiac ultrasound exam.

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.

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DESKi	HeartFocus 510(k) Summary	Apr 4, 2025
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K242807

CONTACT DETAILS	
Applicant Name	DESKi
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Device Trade Name	HeartFocus (v.1.1.1)
Common Name	Radiological acquisition and/or optimization guidance system
Classification Name	Image Acquisition And/Or Optimization Guided By Artificial Intelligence
Regulation Number	892.2100
Product Code	QJU

Legally Marketed Predicate Device	DEN190040 Caption Guidance
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DEVICE DESCRIPTION SUMMARY

The HeartFocus software is a radiological computer-assisted acquisition guidance system that provides real-time user guidance during echocardiography to assist the user in acquiring anatomically standard diagnostic-quality 2D echocardiographic views. HeartFocus software is an accessory to compatible general-purpose diagnostic ultrasound systems.

HeartFocus is intended to be used by medical professionals who have received appropriate training on ultrasound basics and training on using the HeartFocus software, provided by either DESKi or by a trained medical professional while using approved training materials.

It supports the acquisitions of 10 echocardiographic 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 (A4C), Apical 5-Chamber (A5C), Apical 2-Chamber (A2C), Apical 3-Chamber (A3C), Subcostal 4-Chamber (SC-4C), and Subcostal Inferior Vena Cava (SC-IVC).

To allow the acquisition of these views, HeartFocus can connect to an ultrasound system, allowing it to receive a stream of ultrasound images.

The standard views acquired with HeartFocus may be assessed by qualified medical professionals to support their decision-making regarding patient care. The collected exams can be transferred notably using DICOM protocols.

HeartFocus is an application that operates entirely offline, without requiring a cloud server to provide its functionalities. All collected medical data is stored locally on the tablet. This data is never transferred to a server controlled by DESKi.

HeartFocus uses artificial intelligence (AI) to emulate the expertise of sonographers in positioning the probe on the patient's chest and in identifying and recording diagnostic-quality clips.

It proposes 4 major functionalities to assist healthcare professionals in the acquisition of cardiac ultrasound images: Live guidance, Diagnostic-quality view detection, Auto record, and Best-effort record.

Live Guidance

This feature provides real-time cues to the user on how to move the probe on the patient's chest to obtain diagnostic-quality images. The guidance UI is generated by a machine learning model that infers the probe's position relative to the target position, i.e. that would provide

diagnostic-quality images. It emulates how a sonographer would manipulate the ultrasound probe to acquire a diagnostic-quality clip.

Diagnostic-Quality View Detection

This feature detects real-time diagnostic-quality images and informs the user to hold the position and perform automatic recording. This detection is performed by a machine learning model that also allows the grading of the recorded clips. When the probe is well positioned and the image is of diagnostic quality, a triangle surrounding the ultrasound image appears in color shifting from blue (lower quality) to green (higher quality). The user shall hold the position so that an automated recording can be performed.

Auto Record

This feature triggers an automatic recording of a clip when the quality is predicted to be of diagnostic quality for a sufficient amount of time.

When the ultrasound frames are consecutively classified as diagnostic quality for a preset period, the “auto record” feature automatically captures a clip.

The auto-record user interface (UI) element fills itself to encourage the user to hold its position. When the entire auto-record UI element is full, the record is saved and the UI indicates it to the user.

This feature emulates how a sonographer would identify diagnostic-quality clips and record them.

Best-Effort Record (BER)

This feature continually assesses clip quality while the user is scanning and, if the user cannot obtain a clip sufficient for an Auto-Record, the software allows the user to record the highest quality clip obtained so far retrospectively.

Once recorded, the clip is available for a visual review where the user can either save the clip or cancel his action and go back to the acquisition. It emulates how a sonographer would identify the best diagnostic-quality clips retrospectively.

INTENDED USE/INDICATIONS FOR USE

The HeartFocus software is intended to assist and guide medical professionals in the acquisition of cardiac ultrasound images. HeartFocus software is an accessory to compatible general-purpose diagnostic ultrasound systems. Heartfocus guides the acquisition of two-dimensional transthoracic echocardiography (2D-TTE). 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 (A4C), Apical 5-Chamber (A5C), Apical 2-Chamber (A2C), Apical 3-Chamber (A3C), Subcostal 4-Chamber (SC-4C), and Subcostal Inferior Vena Cava (SC-IVC).

HeartFocus software is indicated for use in adult patients who require a cardiac ultrasound exam.

INDICATIONS FOR USE COMPARISON

The indications for use are the same.

TECHNOLOGICAL COMPARISON

Table 1: Predicate table

Parameter	Caption Guidance (DEN 190040)	Proposed HeartFocus	Conclusion
Classification Name	Image Acquisition and/OR Optimization Guided by Artificial Intelligence	Image Acquisition and/OR Optimization Guided by Artificial Intelligence	Same
Product Code	QJU	QJU	Same
Intended Use	The Caption Guidance software is intended to assist medical professionals in the	The HeartFocus software is intended to assist healthcare professionals in the acquisition of cardiac	Same

	acquisition of cardiac ultrasound images. Caption Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems.	ultrasound images. The HeartFocus software is an accessory to compatible general purpose diagnostic ultrasound systems.	
Indications for use	<p>The 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), Apical 2-Chamber (AP2), Apical 3-Chamber (AP3), Subcostal 4-Chamber (SubC4), and Subcostal Inferior Vena Cava (SC-IVC).</p>	<p>The HeartFocus software is indicated for use in two-dimensional transthoracic echocardiography (2DTTE) 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 Muscles (PSAX-PM), Apical 4-Chamber (A4C), Apical 5-Chamber (A5C), Apical 2-Chamber (A2C), Apical 3-Chamber (A3C), Subcostal 4-Chamber (SC-4C), and Subcostal Inferior Vena Cava (SC-IVC).</p>	<p>Same</p> <p>*A4C, A5C, A2C, A3C, SC-4C are the American Society of Echocardiography Acronyms: <u>Guidelines for Performing a Comprehensive Transthoracic Echocardiographic Examination in Adults: Recommendations from the American Society of Echocardiography (asecho.org)</u></p>
Intended User	Medical professionals (including expert sonographers)	Medical professionals (including expert sonographers)	Same
Compatible Ultrasound System and Probe	The uSmart 2300t Plus ultrasound system with the 2300t-compatible Terason 4v2A linear phased array probe	Clarius Scanner PAHD3 (wireless), PAHD, PAL, and Clarius Ultrasound Scanner Software	Substantially Equivalent: Both the predicate devices and the proposed device function as a

			<p>software accessory to a cleared-to-market ultrasound device. Both ultrasound devices are cleared for the diagnostic ultrasound clinical application of acquiring cardiac images 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.</p>
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Clinical Features

<p>Image Acquisition Guidance</p>	<p>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</p>	<p>HeartFocus algorithm provides live-guidance to guide the user on how to position the probe on the patient's chest to obtain diagnostic-quality images</p>	<p>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</p>
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			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: 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	HeartFocus algorithm provides analysis of the diagnostic-quality of the image and indicates to the user when the current frame is diagnostic-quality to hold the position for a recording Further, a score on the expected diagnostic quality of the Auto-Record and Best-Effort-Record clips is indicated such that the user can make decisions to further optimize the quality	Substantially Equivalent
Manual Image Recording	Manual recording	Manual recording if prompted by the user	Same
Automatic Capture of Clips and 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.	Auto-Record: automates the capture of diagnostic-quality recordings, emulating how a sonographer knows when an image is of sufficient quality to be diagnostic and records it.	Substantially Equivalent
Retrospectively Recording of Highest Quality Clip	Save Best Clip: This feature continually assesses clip quality while the user is scanning and, if the user is not able to obtain a clip sufficient for	Best-Effort-Record: this feature stores the clip that has been evaluated as having the best expected diagnostic quality during an exam for a given reference view. If the user	Substantially Equivalent

	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.	does not manage to perform an auto-record for the reference view, the Best-Effort-Record clip is proposed to the user.	
Deep Learning Based Algorithm	Yes	Yes	Same
Machine Learning – Based Algorithm	Yes	Yes	Same

NON-CLINICAL AND CLINICAL TESTS SUMMARY

1- Human Factors Validation Study

A human factors validation study on HeartFocus was conducted following the FDA Guidance Document, « Applying Human Factors and Usability Engineering to Medical Devices » and IEC 62366 1:205 standard. This study aimed to demonstrate that the HeartFocus user interface is safe and effective for the intended users, uses, and use environments. The HeartFocus user interface was developed through a series of preliminary evaluations during its development process to find the best and most effective design. The final version of the device has then been assessed in a summative evaluation.

During this evaluation, the characteristics of the user interface that could affect safety were identified by conducting a task analysis and recorded as use scenarios. 9 use scenarios, representing the primary functions of HeartFocus have been established. Potential errors leading to potential risks in these use scenarios have then been identified. The 7 scenarios concerned were considered “hazard-related” and selected for the usability summative

evaluation, but no risk was identified regarding the health and safety of users.

The summative evaluation was conducted with 31 participants representing the intended users of HeartFocus and included novices (registered nurse) and trained medical professionals (Cardiologists, Sonographers, Intensivists, Emergency Physicians).

User tests were carried out to observe the execution of all hazard-related scenarios. They were performed in an environment representative of the intended use conditions of HeartFocus.

The user tests achieved a high success rate, with 100% success in 4 of the 7 scenarios and 97% success in the remaining 3, providing robust evidence that critical tasks can be performed with high accuracy and minimal risk.

2- Algorithms Performance Testing

Performance testing of the AI/ML algorithms has been conducted to evaluate the effectiveness of the AI/ML features of the HeartFocus software.

In total, AI/ML algorithms were trained and tuned on 1,483 patients and 1,204,113 ultrasound images. 290 patients and 361,104 ultrasound images were used for performance testing. Data collected as part of the clinical trial, containing 240 patients (120 US + 120 non-US), were also employed for additional retrospective evaluation. Both training/tuning data and test data were collected on patients of varying body mass index (BMI), age, and sex.

The main features of the system were tested independently using the primary endpoints described in Table 2. Secondary endpoints were also evaluated to demonstrate the ability of the algorithms to:

- accurately detect anatomical structures of the heart in ultrasound images to indicate whether they can be used to guide the user,
- maximize the likelihood of capturing high-quality records,
- provide a relevant estimate of recording quality,
- automatically record clips identified to be of diagnostic quality by experts,

- guide from one reference view to another.

Subgroup analyses were performed across varying BMI (< 25, ≥ 25 and < 30, ≥ 30), age (< 65, ≥ 65), and sex (male, female).

Table 2: Primary objectives, endpoints, and success criteria

Feature	AI/ML Algorithm	Objective	Endpoint	Success Criteria
Diagnostic-quality view detection	View Classification	Ability to classify ultrasound images with similar accuracy as experts	Cohen's kappa score between the model's predictions and the ground truth labels made by experts (by frame)	Lower bound of the 95% confidence interval of the Cohen's kappa score > 0.6 (substantial agreement) for the 10 reference view
Live guidance	Guidance	Ability to provide successful guidance cues on ultrasound frames	Positive predictive value of successful guidance cues (by frame)	Lower bound of the 95% confidence interval of the positive predictive value > 0.8 for the 10 reference views
Auto record	View Classification + Recording	Ability to save high-quality records according to experts	Positive predictive value of high-quality records among auto-records (by clip)	Lower bound of the 95% confidence interval of the positive predictive value > 0.6 and point estimate of the positive predictive value > 0.8 for the 10 reference views

Diagnostic-quality view detection

Experts (cardiologists and/or experienced sonographers) annotated the ultrasound clips to identify diagnostic-quality images. First annotation was performed by an expert (expert annotator) and was reviewed by a second expert (expert reviewer). When necessary, disagreements were resolved either through direct reconciliation by the 2 experts or by a third expert. The ground truth (or gold standard) was defined from the consensus between the first expert annotator and the expert reviewer(s). For each ultrasound frame, the View Classification model predicts whether it is of diagnostic quality. The evaluation consists of comparing the

agreement between the model predictions and the experts' annotations using Cohen's kappa score.

The evaluation was performed on 30,361 images from 14 patients. Cohen's kappa scores range from 0.699 [0.673, 0.724] to 0.873 [0.861, 0.884], meeting the success criteria of Cohen's kappa score > 0.6 on the lower bound of the 95% CI for each reference view.

Live guidance

Live guidance was evaluated on ultrasound acquisitions where the frame and probe position were collected simultaneously. For a given reference view, each ultrasound frame is at a certain position (called the actual position) regarding the target position (where diagnostic-quality frames are captured). The Guidance model predicts guidance cues to help navigate toward this target position. The evaluation consists of computing the positive predictive value (PPV), which represents the proportion of ultrasound frames where the final position, after following the guidance cues, is closer to the target position than the actual position.

The evaluation was performed on 270,582 images from 20 patients. Guidance cues PPV ranges from 0.810 [0.804, 0.816] to 0.953 [0.951, 0.955], satisfying the success criteria of PPV > 0.8 on the lower bound of the 95% CI for each reference view.

Auto record and Best-effort record

For each reference view, long-duration clips where an operator moves the ultrasound probe and obtains both diagnostic-quality and non-diagnostic-quality frames were collected. Based on the View Classification model's output, the Recording algorithms aim to automatically record diagnostic-quality clips (short duration) that could be saved in the clinical practice. The positive predictive value (PPV) of the Recording algorithms is evaluated for each reference view.

The evaluation was performed on 211 long-duration clips from 34 patients. While using the Auto record feature solely, the PPV ranges from 0.846 [0.665, 0.938] to 1.000 [0.908, 1.000], meeting the success criteria of PPV > 0.6 on the lower bound of the 95% CI and PPV > 0.8 on the point estimate for each reference view. While using both the Auto record and Best-Effort record, the PPV ranges from 0.816 [0.666, 0.908] to 1.000 [0.914, 1.000].

3- Clinical Study

A prospective multicentric clinical study was conducted to evaluate the use of HeartFocus by medical professionals without prior echocardiography training.

Study Design

Eight (8) registered nurses (RNs) were trained and evaluated on their performance to acquire a 10-view 2D-TTE protocol (two-dimensional transthoracic echocardiography). Participants were scanned by the RN (study exam) and 10 standard views were obtained using a Clarius ultrasound system with HeartFocus software: 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 (A4C), Apical-5-Chamber (A5C), Apical-2-Chamber (A2C), Apical-3-Chamber (A3C), Subcostal-4-Chamber (SC-4C), and Subcostal Inferior Vena Cava (SC-IVC). The study continued enrollment until the eight RNs had completed scans of 30 patients each. For comparison, participants were also scanned to obtain the same 10 views by a trained medical professional without cardiac guidance and using the same Clarius ultrasound system (control exam).

Following the study and control exams, a panel of five (5) expert cardiologist readers (not the same as the ones scanning the patients) independently provided assessments of whether the patient study, in its totality, provided sufficient information to assess 12 clinical parameters. In addition, this panel of five (5) expert cardiologist readers also independently evaluated if the diagnostic image quality per clip was sufficient for clinical interpretation using the ACEP scale (ACEP \geq 3, Liu, R. B. et al. Emergency Ultrasound Standard Reporting Guidelines); the cardiologists graded each clip. The readers were blinded to assessments from other panel members as well as to which site the images were obtained and whether the images were obtained by an RN or a trained medical professional (sonographer or cardiologist). The results from the expert panel reads were used for the statistical analysis.

To reduce possible sources of bias in the design, the RNs, sonographers, and cardiologists were all blinded to results determined by others.

Four (4) prospectively defined primary endpoints were evaluated sequentially for the study, all of which assessed whether the patient study exam conducted by the RN, taken as a whole, was of sufficient image quality to visually make these clinical assessments. Specifically, the endpoints assessed whether, in the judgment of expert cardiologists, the studies permitted qualitative visual assessment of left ventricular (LV) size, LV function, right ventricular (RV) size, and the presence of non-trivial pericardial effusion. In addition, expert cardiologist readers performed a qualitative and quantitative assessment of the ultrasound measurements. They visually determined the presence of LV or RV hypertrophy, dilation of the left or right ventricle or atrium, abnormal LV or RV function, abnormal mitral or tricuspid or aortic valve (i.e. structurally normal, abnormal, suspected device), pericardial effusion, dilatation of the IVC or any other abnormality. The cardiologists also measured the LV end-systolic and end-diastolic volumes and function. On parasternal analysis, they measured the septal and posterior wall thickness, the internal diameter of the LV (systole and diastole), as well as the aortic root. The diameter of the IVC was also evaluated. The acquisition time for the limited ultrasound exam for the novices was also collected.

Results

A total of 240 adults aged 22 years and older who were scheduled for a clinically indicated echocardiography examination at one of the two investigation centers were included in this study, with 120 patients at Site 1 (France) and 120 patients at Site 2 (USA).

The four primary endpoints were satisfied and demonstrated the clinical utility of HeartFocus guidance for medical professionals without specialized echocardiography training. Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to make clinical assessments in the proportion of study exams conducted, as shown below.

Table 3: Primary endpoint results

Endpoint	Percent of diagnostic quality % [95% Wilson CI*]
Qualitative Visual Assessment of LV Size	100 [98.4;100]
Qualitative Visual Assessment of LV Function	100 [98.4;100]

Qualitative Visual Assessment of RV Size	100 [98.4;100]
Qualitative Visual Assessment of Non-Trivial Pericardial Effusion	100 [98.4;100]

*Wilson Score method is used due to the point estimate is at or near borderline of 100%

Secondary endpoints and additional analyses presented below were not evaluated based on a specific hypothesis. Since the evaluation of secondary endpoints and additional analyses did not allow for control of Type I error, the study results are presented as a descriptive demonstration of the use of HeartFocus guidance for the specific secondary endpoints and additional analyses.

Additional secondary endpoints were evaluated and demonstrated the robustness of the data, including eight (8) additional patient-level clinical parameters evaluated and each had a high proportion of scans considered to be of sufficient image quality to make each of the eight (8) additional patient-level clinical parameter assessments, i.e., qualitative visual assessment of RV function, inferior vena cava (IVC) size, left atrial (LA), right atrial (RA) size, aortic valve (AV), mitral valve (MV), tricuspid valve (TV) and segmental kinetics of the LV.

Specifically, the eight (8) RNs acquired echocardiographic exams of sufficient image quality to visually make clinical assessments in the proportion of study exams conducted, as shown below.

Table 4: Secondary endpoint results

Endpoint	Percent of diagnostic quality % [95% Wilson CI*]
Qualitative Visual Assessment of RV Function	99.6 [97.7;99.9]
Qualitative Visual Assessment of LA Size	100 [98.4;100]
Qualitative Visual Assessment of RA Size	98.8 [96.4;99.6]
Qualitative Visual Assessment of Segmental Kinetics of the LV	95.4 [92.0;97.4]
Qualitative Visual Assessment of AV	98.8 [96.4;99.6]

Qualitative Visual Assessment of MV	100 [98.4;100]
Qualitative Visual Assessment of TV	95.4 [92.0;97.4]
Qualitative Visual Assessment of IVC Size	78.3 [72.7;83.1]

*Wilson Score method is used due to the point estimate is at or near borderline of 100%

In addition to assessing if image quality was sufficient to make assessments, cardiologists also made specific qualitative visual assessments based on the study and control exams (e.g., presence or absence of non-trivial pericardial effusion). The proportion of scans in which the diagnostic decision was the same between study and control exams was very high, further demonstrating the usability of HeartFocus guidance. For primary clinical parameters, the range was 87.5% to 98.3%. Similarly, for secondary clinical parameters, the range was 87.1% to 99.6%.

To provide a robust assessment of the performance of HeartFocus guidance, subjects enrolled in the study included a broad range of patient characteristics representative of the intended use population. The standard of care echo revealed a high proportion of cardiac abnormalities (70.4%). In addition, many of the study patients were inpatients or had other challenging characteristics, such as high BMI (59.6% with BMI > 25) and cardiac implantable devices (18.8%).

Subgroup analyses were conducted to evaluate the impact of specific baseline and demographic characteristics (i.e., BMI, presence of known cardiac abnormalities, scan sequence number within each acquiring nurse, and study site) on the outcomes of the primary and secondary endpoints. The results demonstrated consistent performance across subgroups.

Furthermore, it was evaluated whether the RN users were able to obtain a high proportion of clips that were considered diagnostic quality. Specifically, the eight (8) RNs acquired echocardiographic clips of diagnostic-image quality for each of the standard views in the following proportion of study exams conducted.

Table 5: Study results: diagnostic-quality clips

View	Percent of diagnostic quality % [95% Wilson CI*]
PLAX	97.5 [94.7;98.8]
PSAX-AV	89.2 [84.6;92.5]
PSAX-MV	90.8 [86.5;93.9]
PSAX-PM	97.1 [94.1;98.6]
A4C	96.2 [93.0;98.0]
A5C	93.3 [89.4;95.9]
A2C	82.5 [77.2;86.8]
A3C	90.0 [85.6;93.2]
SC-4C	89.2 [84.6;92.5]
SC-IVC	77.5 [71.8;82.3]

*Wilson Score method is used due to the point estimate is at or near borderline of 100%

The objective was to acquire 10 clips per patient, so in total, 2400 clips. Novices recorded 2362 clips and missed 38 clips. Among the recorded clips, 67.4% of the clips were saved with the “Auto record” feature, 21.3% with the “Best-effort record” feature, and 11.3% with the “manual record” feature.

99.7% of the clips recorded with the “Auto record” feature were of diagnostic quality, demonstrating the high specificity of this feature. 93.9% of the clips recorded with the “best-effort record” feature were of diagnostic quality, and 40.5% of the clips recorded with the “manual record” feature were of diagnostic quality.

The average acquisition time per limited exam for novices in both centers was 23.6 ±10.6 minutes.

PREDETERMINED CHANGE CONTROL PLAN

HeartFocus could expand its compatibility to additional ultrasound systems and additional operating systems. This will be addressed through 3 modifications in the Predetermined Change Control Plan (PCCP).

- M1 - Retraining of the core algorithms: This modification's scope is the retraining of the AI/ML models in the perspective of validating a new manufacturer prior to an M2. The modification is limited to retraining with additional data without changing the models' architecture or training procedure. It notably describes the data collection to retrain the models and the evaluation plan to validate the performance of the retrained models on the already-cleared ultrasound systems.
- M2 - Extend the use of the ML-DSF with new ultrasound systems: This modification's scope is the validation of HeartFocus on new ultrasound systems. It notably describes the data collection and evaluation plan to validate the performance of the AI/ML models on the new ultrasound system.
- M3 - Extend the use of the ML-DSF with new operating systems: This modification's scope is the extension of the compatibility with new operating systems.

M1 and M2 will both be triggered when DESKi makes a partnership with a new ultrasound manufacturer, and will always be performed together.

Table 6 describes, for each modification, its rationale and how it will be tested to ensure the safety and effectiveness of the device after the modification.

Table 6: Rationale and testing for each modification

Modification	Rationale	Testing
M1 - Retraining of the core algorithms	Enhance the performance of the AI models in the perspective of extending the use of the ML-DS with new ultrasound systems	Execute AI performance on the reference test set and system-level validation tests
M2 - Extend the use of the ML-DSF with new ultrasound systems	Enable support for a broader range of ultrasound systems	Execute AI performance tests on new system test set and system-level validation test
M3 - Extend the use of the ML-DSF with new operating systems	Enable support for a broader range of devices	Execute system-level validation test

Table 7 describes the requirements for the ultrasound systems that can be cleared through the PCCP (M1+M2).

Table 7: Ultrasound system requirements

Requirement	Description
FDA-cleared ultrasound system compatible with HeartFocus' intended use	<ul style="list-style-type: none"> ● Ultrasound system shall be FDA-cleared ● Validated for cardiac use ● Validated for use on adults
Integration features	<ul style="list-style-type: none"> ● Technical integration shall allow HeartFocus to access live ultrasound stream ● Compatible for an integration on HeartFocus' operating systems
Minimal specifications	<ul style="list-style-type: none"> ● The ultrasound system shall provide an image stream at a minimum of 15 frames per second. ● Center or nominal frequency within 2–5 MHz, suitable for adult transthoracic echocardiography ● At least 30 cm depth, to allow full visualization of adult cardiac structures ● 2D B-mode imaging (grayscale) ● Cone-shaped field of view with an opening angle of at least 80 degrees

For each M1+M2, at least 20 new patients (~270k frames) collected with the new ultrasound system will be added to the train set to retrain the AI/ML models. The hyperparameters will be tuned for the retraining of the AI/ML algorithms (if necessary). Additional testing data will be collected on the new ultrasound system to validate it. 40 US patients (~400 clips) and 40 non-US (~540k frames) patients will be included, ensuring that at least 25% of patients have a BMI ≥ 30 kg/m².

The performance of the retrained algorithms will be validated on: the reference test set (used in the initial 510(k) submission), the test set(s) collected for the validation of ultrasound systems through previous M1+M2 (if applicable), and the new test set collected on the new ultrasound system. Performance testing on all these data should meet the success criteria defined in Table 8. Performance testing will integrate subgroup analysis on the ultrasound system.

Table 8: Primary objectives, endpoints, and success criteria for M1+M2 modifications.

Feature	AI/ML Algorithm	Objective	Endpoint	Success Criteria
Diagnostic-quality view detection	View Classification	Ability to classify ultrasound images with similar accuracy as experts	Cohen's kappa score between the model's predictions and the ground truth labels made by experts (by frame)	Lower bound of the 95% confidence interval of the Cohen's kappa score > 0.6 (substantial agreement) for the 10 reference view
Live guidance	Guidance	Ability to provide successful guidance cues on ultrasound frames	Positive predictive value of successful guidance cues (by frame)	Lower bound of the 95% confidence interval of the positive predictive value > 0.8 for the 10 reference views
Auto record	View Classification + Recording	Ability to save high-quality records according to experts	Positive predictive value of high-quality records among auto-records (by clip)	Lower bound of the 95% confidence interval of the positive predictive value > 0.6 and point estimate of the positive predictive value > 0.8 for the 10 reference views

In case M1+M2 fails (success criteria are not met), a single second iteration of M1+M2 will be performed. For the second iteration, the algorithm will be retrained using the existing training dataset and the non-US testing data (40 patients from the new ultrasound system) collected during the first M1+M2 iteration. A new test set of 40 non-US patients and 40 US patients will be collected using the new ultrasound system. The algorithm will then be evaluated using this new test set as well as the reference test set used in the initial 510(k) submission (34 patients from the standalone study and 240 patients from the clinical study, using retrospective analysis) and the test set(s) collected for the validation of previously cleared ultrasound systems (40 US + 40 non-US patients for each previously cleared ultrasound systems). If the second iteration of M1+M2 is not successful, the extension to the new ultrasound system will not be carried out through this PCCP. Each iteration of M1+M2 will be documented.

CONCLUSION

The HeartFocus software is similar in its technological features to its predicate device, Caption Guidance (DEN 190040). Both systems are intended as an assistive tool to aid medical professionals in the acquisition of cardiac ultrasound images, citing the same echocardiographic views. Both systems apply deep learning based algorithms to emulate the expertise of a sonographer by providing real-time guidance on how to position the transducer on the patient's body. Both are installed on a third-party, previously cleared ultrasound device. There are minor technological differences between the subject and the predicate device, such as the compatible scanner probe and minor differences in how guidance is provided to the user, however, these differences do not raise new or different questions of safety or effectiveness since the principal technology on which the device is based is similar. Thus, Heartfocus is substantially equivalent.