January 15, 2025

Caption Health, Inc.
Tahir Rizvi
Sr. Director of Regulatory Affairs
4 West 4th Avenue
Suite 215
San Mateo, California 94402

Re: K243065
Trade/Device Name: Cardiac Guidance
Regulation Number: 21 CFR 892.2100
Regulation Name: Radiological Acquisition And/Or Optimization Guidance System
Regulatory Class: Class II
Product Code: QJU
Dated: December 11, 2024
Received: December 16, 2024

Dear Tahir Rizvi:

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243065

Device Name

Cardiac Guidance

Indications for Use *(Describe)*

The Cardiac Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. Cardiac Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems.

The Cardiac 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).

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.

GE HealthCare
Caption Health

K243065

510(k) Summary

Name of Device: Cardiac Guidance
Classification Name: Image Acquisition And/Or Optimization Guided By Artificial Intelligence
Regulatory Class: II
Product Code: QJU
Regulation: 21 CFR 892.2100
Predicate Device: Caption Guidance
Device Description:

The Cardiac Guidance software is a radiological computer-assisted acquisition guidance system that provides real-time guidance during echocardiography to assist the user capture anatomically correct images representing standard 2D echocardiographic diagnostic views and orientations. This AI-powered, software-only device emulates the expertise of skilled sonographers.

Cardiac Guidance is comprised of several different features that, combined, provide expert guidance to the user. These include:

- Quality Meter: The 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.

- Prescriptive Guidance: The prescriptive guidance feature in Cardiac Guidance provides direction to the user to emulate how a sonographer would manipulate the transducer to acquire the optimal view.

- Auto-Capture: The Cardiac 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.

- 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.

Intended Use/ Indications for Use:

No differences exist between the subject device of this PCCP and the predicate device with respect to intended use or indications for use. The following summary of intended use/ indications for use is reproduced here for reference:

> The Cardiac Guidance software is intended to assist medical professionals in the acquisition of cardiac ultrasound images. The Cardiac Guidance software is an accessory to compatible general purpose diagnostic ultrasound systems.

The Cardiac 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).

Summary of Technological Characteristics compared to the previously-cleared PCCP:

The updated PCCP expands upon the existing list of changes from the most recent 510(k) clearance (K201992).

Performance Data and Performance Testing

Safety and performance of the Cardiac Guidance software will be evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing outlined in the submission. Compared to previously-cleared PCCP, two new tests have been incorporated to support validation of the modified device.

The following Table briefly compares the modifications between the previously-cleared PCCP and the subject PCCP of this submission.

Modification	K201992 PCCP	Subject PCCP
Real-Time Guidance for Additional 2D TTE Views	Added cardiac views to standard echocardiography views, focusing on various anatomical regions (e.g., PLAX, PSAX, Apical, Subcostal, Suprasternal).	Expands the list of views in previously authorized PCCP by adding additional standard cardiac *subset views*. These additional cardiac ultrasound views are focused on enhanced diagnostic imaging and coverage of specific anatomical regions.
Labeling compatibility of new compatible ultrasound systems and UI Enhancement	Ensured software compatibility with ultrasound systems of similar screen sizes.	Builds on compatibility with additional UI/UX improvements, incl. support for various screen sizes such as mobile platforms.
Non-expert Validation	Not included.	Adds standalone test protocol to enable validation of modified device performance by the intended user groups, ensuring equivalency to the original device based on predefined clinical endpoints.
Human Factors Test	Not included.	Introduces Human Factors Testing to evaluate user interactions and ensure critical tasks remain unaffected by UI/UX modifications.

The revised PCCP does not introduce new or different questions of safety and effectiveness compared to the predicate device. Accordingly, the Cardiac Guidance software is determined to be substantially equivalent.

Summary of planned modifications, testing methods, validation activities and performance requirements

This 510(k) submission outlines future algorithm improvements under an updated Predetermined Change Control Plan (PCCP) and seek authorization of this updated PCCP. The plan details anticipated software modifications, methods and validation criteria that will be utilized to implement those modifications in a controlled manner and ensure the subject device remains as safe and effective as the predicate. Anticipated software modifications are discussed in detail in the main submission and are summarized in the table below, as well as a modification protocol describing the verification and validation activities that will support these planned modifications. The modification protocol incorporates impact assessment considerations and specifies requirements for data management, including data sources, collection, storage, and sequestration, as well as documentation and data segregation/re-use practices.

The test methods specified in the PCCP establish substantial equivalence to the predicate device, and include sample size determination, analysis methods, and acceptance criteria. To ensure validation test datasets are representative of the intended use population, each will meet minimum demographic requirements. Caption Health shall communicate product changes made under the scope of this PCCP to end-users via customer and software update notifications, as well through updated product labeling.

A summary of these software modifications, rationale and test methods are presented in the table below:

Modification	Rationale	Testing Methods
Retraining/optimization/ modification of core algorithm(s)	These changes enhance model robustness, reduce bias, improve generalizability, and enable Caption Health to respond effectively real-world feedback.	Repeating verification tests and the system level validation test to ensure the pre-defined acceptance criteria are met.
Real-time guidance for additional 2D TTE views: This modification expands the list of views by adding additional cardiac subset views	These changes enhance the system's diagnostic capabilities by providing more focused, specific views that assist expert clinicians in making more accurate cardiac assessments, improving overall usability.	Repeating verification tests and two system level validation tests including usability testing to ensure the pre-defined acceptance criteria are met for the additional views.
Optimization of the core algorithm(s) implementation in the software such as optimization of algorithm thresholds, averaging logic, transfer functions, frequency, and refresh rate	These optimizations improve the performance of the algorithm, making it more efficient and accurate without changing its fundamental functionality, ensure consistency across different devices and enhance the usability of the device	Repeating relevant verification test(s) and the system level validation test to ensure the pre-defined acceptance criteria are met.
Addition of new types of prescriptive guidance for existing views such as patient positioning and breathing guidance, guidance	These changes provide additional real-time feedback to users enhances system's utility and user experience in obtaining diagnostic	Repeating relevant verification tests and two system level validation tests including usability

that combines two or more physical probe movements, pressure and probe sliding/angling and addition of existing guidance types to all existing views in the device and future views	quality images.	testing to ensure the pre-defined acceptance criteria are met.
Labeling compatibility of software with compatible ultrasound systems for various screen sizes including mobile platforms or/and change in the user interface features, such as addition of Prescriptive Guidance audio and configurability of guidance features.	These changes enable support for a broader range of devices and are intended to enable an enhanced user experience without compromising critical tasks.	Repeating relevant verification tests and the system level validation test including usability testing to ensure the pre-defined acceptance criteria are met.

Conclusions:

The current iteration of the Cardiac Guidance software is as safe and effective as the previous iteration of such software. The Cardiac Guidance software is substantially equivalent in intended use, design, principles of operation, technological characteristics, and safety features to the predicate device. There are no different questions of safety and/or effectiveness introduced by the Caption Guidance software when used as intended. Thus, the Cardiac Guidance software is substantially equivalent. The activities proposed within the Modification Protocol will continue to reasonably ensure the safe and effectiveness of the product, and all modifications will maintain the device within stated intended use and indications for use.

The purpose of this 510(k) submission is to seek a focused review and clearance of an updated predetermined change control plan (PCCP) that outlines anticipated modifications to the device and the methods that will be utilized to implement those modifications in a controlled manner while maintaining safety and efficacy. This current submission expands on the predetermined change control plan (PCCP) previously cleared under K201992, which was itself an update to the initial PCCP authorized as part of DEN190040.