Caption Health
℅ Sam Surette
Head of RA/QA
2000 Sierra Point Pkwy., 8th Floor
BRISBANE CA 94005

September 18, 2020

Re: K201992
Trade/Device Name: Caption Guidance
Regulation Number: 21 CFR 892.2100
Regulation Name: Radiological acquisition and/or optimization guidance system
Regulatory Class: Class II
Product Code: QJU
Dated: July 17, 2020
Received: July 17, 2020

Dear Sam Surette:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201992

Device Name

Caption Guidance

Indications for Use *(Describe)*

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

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).

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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510(k) SUMMARY

Caption Health, Inc.'s

Caption Guidance Software

Submitter

Caption Health, Inc.
2000 Sierra Point Parkway, 8th Floor
Brisbane, CA 94005

Contact Person: Sam Surette, Head of RA/QA

Phone: (415) 671-4711

Email: sam@captionhealth.com

Date Prepared: July 17, 2020

Name of Device: Caption Guidance

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

Regulatory Class: II

Product Code: QJU

Predicate Device: Caption Guidance (K200755)

Device Description:

The Caption Guidance software is a radiological computer assisted acquisition guidance system that provides real-time user guidance during acquisition of echocardiography to assist the user in obtaining anatomically correct images that represent standard 2D echocardiographic diagnostic views and orientations. Caption Guidance is a software-only device that uses artificial intelligence to emulate the expertise of sonographers.

Caption 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 Caption Guidance provides direction to the user to emulate how a sonographer would manipulate the transducer to acquire the optimal view.
- **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.

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

Summary of Technological Characteristics:

The Caption Guidance software is identical to the predicate device, and as such, the technological characteristics are incorporated by reference.

Conclusions

The current iteration of the Caption Guidance software is as safe and effective as the previous iteration of such software. The Caption Guidance software has the same intended use, indications for use, technological characteristics, and principles of operation as its predicate device. Thus, the Caption Guidance software is substantially equivalent.

The purpose of the 510(k) submission is to address the modification of a predetermined change control plan (PCCP) to outline anticipated modifications to the Caption Guidance software and the methods that will be utilized to implement those modifications in a controlled manner while maintaining safety and efficacy. In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the software to the field. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field.