February 7, 2020

Caption Health, Inc.
Sam Surette
RA/QA Manager
2000 Sierra Point Parkway
8th Floor
Brisbane, CA 94005

Re: DEN190040
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: August 27, 2019
Received: August 27, 2019

Dear Sam Surette:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Caption Guidance, a prescription device under 21 CFR Part 801.109 with the following indications for 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 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).

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov. FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Caption Guidance, and substantially equivalent devices of this

generic type, into Class II under the generic name radiological acquisition and/or optimization guidance system.

FDA identifies this generic type of device as:

> **Radiological acquisition and/or optimization guidance system** – A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On August 27, 2019, FDA received your De Novo requesting classification of the Caption Guidance. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Caption Guidance into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Caption Guidance can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Device Error – Failure to provide guidance on acquiring diagnostic-quality images or signals, leading to delay, prolonged examination, or additional unnecessary procedures, due to: • Algorithm failure • Hardware or software failure	• Design verification and validation • Labeling
User Error – Operator failure to follow the guidance provided by the device to acquire diagnostic-quality images or signals, leading to	• Design verification and validation • Labeling

delay, prolonged examination, or additional unnecessary procedures, due to human error	

In combination with the general controls of the FD&C Act, the radiological acquisition and/or optimization guidance system is subject to the following special controls:

1. Design verification and validation must include:
    a. A detailed, technical device description, including a detailed description of the impact of any software and hardware on the device's functions, the associated capabilities and limitations of each part, and the associated inputs and outputs.
    b. A detailed, technical report on the non-clinical performance testing of the subject device in the intended use environments, using relevant consensus standards when applicable.
    c. A detailed report on the clinical performance testing, obtained from either clinical testing, accepted virtual/physical systems designed to capture clinical variability, comparison to a closely-related device with established clinical performance, or other sources that are justified appropriately. The choice of the method must be justified given the risk of the device and the general acceptance of the test methods. The report must include the following:
        i. A thorough description of the testing protocol(s).
        ii. A thorough, quantitative evaluation of the diagnostic utility and quality of images/data acquired, or optimized, using the device.
        iii. A thorough, quantitative evaluation of the performance in a representative user population and patient population, under anticipated conditions and environments of use.
        iv. A thorough discussion on the generalizability of the clinical performance testing results.
        v. A thorough discussion on use-related risk analysis/human factors data.
    d. A detailed protocol that describes, in the event of a future change, the level of change in the device technical specifications or indications for use at which the change or changes could significantly affect the safety or effectiveness of the device and the risks posed by these changes. The assessment metrics, acceptance criteria, and analytical methods used for the performance testing of changes that are within the scope of the protocol must be included.
    e. Documentation of an appropriate training program, including instructions on how to acquire and process quality images and video clips, and a report on usability testing demonstrating the effectiveness of that training program on user performance, including acquiring and processing quality images.

2. The labeling required under 21 CFR 801.109(c) must include:
    a. A detailed description of the device, including information on all required and/or compatible parts.
    b. A detailed description of the patient population for which the device is indicated for use.
    c. A detailed description of the intended user population, and the recommended user training.
    d. Detailed instructions for use, including the information provided in the training program used to meet the requirements of paragraph (1)(e).
    e. A warning that the images and data acquired using the device are to be interpreted only by qualified medical professionals.
    f. A detailed summary of the reports required under paragraphs 1(b) and 1(c).
    g. A statement on upholding the As Low As Reasonably Achievable (ALARA) principle with a discussion on the associated device controls/options.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the radiological acquisition and/or optimization guidance system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Shahram Vaezy at 301-796-6242.

Sincerely,

Robert Ochs, Ph.D.
Deputy Director for Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health