Caption Health
℅ Savannah Hari
Quality Systems Manager
Manatt, Phelps & Phillips, LLP
1 Embarcadero Center, 30th Floor
San Francisco, California 94111

January 19, 2022

Re: K210747
Trade/Device Name: Caption Interpretation Automated Ejection Fraction Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: January 18, 2022
Received: January 18, 2022

Dear Savannah Hari:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210747

Device Name

Caption Interpretation Automated Ejection Fraction Software

Indications for Use *(Describe)*

The Caption Interpretation Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.

The Caption Interpretation Automated Ejection Fraction Software is indicated for use in adult patients.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Caption Health, Inc.
Caption Interpretation Automated Ejection Fraction
K210747

Submitter

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

Contact Person: Savannah Hari, Quality Systems Manager

Phone: (415) 671-4711
Email: savannah@captionhealth.com
Date Prepared: January 14, 2022

Device

Proprietary Name: Caption Interpretation Automated Ejection Fraction Software

Common Name: Caption Interpretation Automated Ejection Fraction Software

Classification Name and Number: Medical Image Management and Processing System, 21 CFR 892.2050

Regulatory Class: II

Product Code: QIH, Automated Radiological Image Processing Software

Predicate Device

Caption Health, Inc. Caption Interpretation Automated Ejection Fraction Software (K200621)

Device Description:

The Caption Interpretation Automated Ejection Fraction Software ("AutoEF") applies machine learning algorithms to process echocardiography images in order to calculate left ventricular ejection fraction. The cleared Caption Interpretation AutoEF performs left ventricular ejection fraction measurements using apical four chamber or apical two chamber cardiac ultrasound views, or the parasternal long-axis cardiac ultrasound view in combination with an apical four chamber or two chamber view. The software selects the image clips to be used, performs the AutoEF calculation, and forwards the results to the desired destination for clinician viewing. The output of the program is the Ejection Fraction estimate stated as a percentage, along with an indication of confidence regarding that estimate.

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 intended use / indications for use are provided below:

> The Caption Interpretation Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation.
>
> The Caption Interpretation Automated Ejection Fraction Software is indicated for use in adult patients.

Summary of Technological Characteristics:

The Caption Interpretation Automated Ejection Fraction Software is an updated version of the predicate device and features very similar technological characteristics. Specific changes between the subject device and the predicate include:

- An additional 30% of training data from three ultrasound devices and two clinical sites for retraining of algorithms
- Simplification of network architecture via simple pooling layers and quantization
- Simplification of image quality algorithms via linear support vector machines
- Optimization of image quality thresholds to maintain performance of the subject device
- Runtime speed optimization of image preprocessing and removal of vestigial code

These particular changes are intended to:

1) Improve the function of the product across the diversity of ultrasound devices in use and patient types in the population.
2) Reduce the complexity of computations, enabling the algorithm to run faster and allow it potentially to operate on lower computing power hardware platforms.
3) Maintain optimal clinical performance and acceptability due to additional network training.

The technological principle underlying both the current version of Caption Interpretation Automated Ejection Fraction Software and the predicate device remains the same, in that both the subject device and predicate enable the calculation of ejection fraction (EF) on previously acquired cardiac scans using machine learning-based algorithms and biplane apical echocardiographic images. Further details can be found in the comparison table below.

Performance Data:

The Caption Interpretation Automated Ejection Fraction Software was developed and tested in accordance with Caption Health's Design Control processes and has been subjected to extensive safety and performance testing. Verification and validation testing was conducted to demonstrate the substantial equivalence of the subject device to the predicate. The primary success criterion was that the subject device would produce an ejection fraction number with a Root Mean Square Deviation below a set threshold as compared to the reference ground truth EF. The same test protocols, acceptance criteria and endpoints were used between the predicate and the subject device to ensure that performance could be appropriately compared.

Non-clinical verification and validation test results established that the device meets its design requirements and intended use. Extensive algorithm development and software verification testing assessed the performance of the software's image video clip selection function, performance characteristics of the algorithm, including AutoEF accuracy and overall functional performance.

Images and cases used for verification and validation testing were carefully separated from training datasets.

A formal retrospective, non-interventional validation study was conducted using over 186 acquired studies where the biplane method of disks ejection fraction was reported. This patient dataset was constructed to provide a balanced range of gender, ejection fraction values, and body mass index levels. Testing included a wide array of ultrasound system manufacturers to verify that the subject device performs acceptably across multiple scanner platforms. The ejection fraction measurements from the subject device were compared to the biplane method ejection fraction, and a root mean square deviation was calculated and used as the primary endpoint. The primary endpoint for the subject device was met (results: 7.21 RMSD EF% [95% CI]), and demonstrated slightly improved performance compared to the predicate device (results: 7.94 RMSD EF % [95% CI]). Performance improvements between the subject device and the predicate device did not lead to significant differences in the outlier rate, with comparable performance between the subject device [1.09% for EF error >15%, 0.55% for EF error >20%] and the predicate [1.61% for EF error >15%, 0% for EF error >20%]. Based on the clinical performance as documented in this retrospective validation study, the device has a safety and effectiveness profile that is substantially equivalent to the predicate device.

Conclusions:

Performance testing demonstrated that the Caption Interpretation Automated Ejection Fraction Software performs as expected and in a manner that is substantially equivalent to the predicate device. The Caption Interpretation Automated Ejection Fraction software has the same intended use, indications for use, and principles of operation as its predicate device. Thus, the Caption Interpretation Automated Ejection Fraction software is substantially equivalent to its predicate.

Comparison of Features between Proposed Subject Device and Predicate Device		
	Caption Health, Inc., Caption Interpretation Automated Ejection Fraction ("AutoEF 2.5") (K210747) - Proposed Device	**Caption Health, Inc., Caption Interpretation Automated Ejection Fraction Software Application ("AutoEF 2.0") (K200621) - Predicate Device**
Product Code	QIH	QIH
Intended Use	The Caption Health, Inc. Caption Interpretation Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation. The Caption Interpretation Automated Ejection Fraction Software is indicated for use in adult patients.	The Caption Health, Inc. Caption Interpretation Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac ultrasound images, to store images, and to manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system in order to provide automated estimation of left ventricular ejection fraction. This measurement can be used to assist the clinician in a cardiac evaluation. The Caption Interpretation Automated Ejection Fraction Software is indicated for use in adult patients.
General Principles of Operation		
Machine Learning- Based Algorithm	Yes	Yes
Operates on DICOM clips	Yes	Yes

Automation level	Fully automated, including clip selection	Fully automated, including clip selection
User Alert to Use Multiple Views	Yes	Yes
Automated Ejection Fraction Calculation	Yes	Yes
Ejection Fraction reported	Whole number estimate	Whole number estimate
Quantitative feedback to enable clinician to assess EF calculation	● Confidence Metric ● Qualitative Bin Likelihood	● Confidence Metric ● Qualitative Bin Likelihood
EF Result shown with video clip	Yes	Yes
User confirmation/ rejection of result	Yes	Yes
Technological Characteristics		
Network Architecture	Simple Pooling	Advanced Pooling
Regressor algorithm	Linear Support Vector Machine	Radial-basis-function (RBF) Support Vector Machine
Image Processing	Grayscaling done first and integer resizing.	Floating point resizing and grayscaling done at the end