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

July 22, 2020

Re: K200621
Trade/Device Name: Caption Interpretation Automated Ejection Fraction Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: QIH
Dated: June 24, 2020
Received: June 24, 2020

Dear Mr. 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)*

K200621

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.

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510(k) SUMMARY
K200621
Caption Health Inc.'s

Caption Interpretation Automated Ejection Fraction Software

Submitter's Name, Address, Telephone Number, Contact Person

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: June 24, 2020

Name of Device

Common or Usual Name: Picture Archival and Communications Systems Workstation

Proprietary Name: Caption Interpretation Automated Ejection Fraction Software

Classification Name: 21 CFR § 892.2050

Regulatory Class: II

Product Code: QIH, Automated Radiological Image Processing Software

Predicate Device

Bay Labs, Inc. EchoMD Automated Ejection Fraction Software (K173780)

Device Description

The Caption Interpretation Automated Ejection Fraction Software applies machine learning algorithms to process echocardiography images in order to calculate left ventricular ejection fraction. Caption Interpretation AutoEF performs left ventricular ejection fraction measurements using the apical four chamber, apical two chamber or parasternal long-axis cardiac ultrasound views or a combination of those views. 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 indications of confidence regarding that estimate.

Intended Use / Indications for Use

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.

The intended use/indications for use statement has been slightly updated compared to the predicate device in order to acknowledge that the software may be located on an ultrasound device in addition to personal computer or PACS system. This minor adjustment in indications for use does not alter the intended use of the product and is substantially equivalent to the predicate.

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. Both products use machine learning algorithms to select clips from those available and for producing an estimation of ejection fraction. Caption Interpretation AutoEF can estimate ejection fraction from a wider range of views, and minor modifications have been made to the methodology for selecting clips. The algorithms for estimating ejection fraction have been further optimized though additional training. None of the differences raise different questions of safety or effectiveness and available data demonstrate that Caption Interpretation performs in a substantially equivalent manner.

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. Software verification and validation test results established that the device meets its design requirements and intended use. Specifically, software verification was conducted at unit, module, and system integration levels. 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, risk management, and overall functional performance. Images and cases used for verification testing were carefully separated from training algorithms.

In addition, AutoEF has undergone multiple tests and studies to demonstrate the acceptable performance. A Clip Annotator study verified the ability of the software to receive, annotate and select clips for interpretation by the AutoEF Calculation Service. Results of the Clip Annotator were compared

to evaluation by a panel of expert readers. That study met the pre-defined acceptance criteria and found that the observed PPV point estimates for the Clip Annotator were greater than 97% for identification of the imaging mode and the view. Similarly, observed sensitivity point estimates were greater than 90% across views and imaging mode.

Caption Interpretation AutoEF was also the subject of a pivotal clinical investigation to validate successful performance of the EF calculation in comparison to conventional EF calculation methods. This testing showed that AutoEF, including clip selection and calculation together, performs as expected and in a manner that is substantially equivalent to the predicate device. Specifically, the primary endpoint evaluating the relationship (RMSD) between AutoEF derived values based on the best available view combination and the reference method met the predetermined acceptance criteria. Secondary hypothesis testing evaluating combinations of views (i.e., EF estimation based on two or more views of AP2, AP4 or PLAX) met the same predetermined acceptance criteria. Single-view EF estimation based on the AP4 view was also observed to be less than the acceptance criterion, and superior to physicians in making a qualitative and quantitative visual assessment. The AP2 and PLAX views observed results did not meet the acceptance criteria, but performed superior on a quantitative visual assessment. Furthermore, the AP2-only and PLAX-only RMSD was observed to be lower than the RMSD of sonographers' biplane tracing before a cardiologist overread.

Finally, testing of the confidence metric functionality verified successful performance of the Confidence Metric in estimating the error range of the EF estimates around the reference EF with evidence that the difference between the estimated EF and the reference EF is normally distributed.

Taken together, the performance testing demonstrates that the Caption Interpretation Automated Ejection Fraction Software performs as expected and in a manner that is substantially equivalent to the predicate device.

Conclusions

The Caption Interpretation Automated Ejection Fraction Software has the same intended use and nearly identical indications compared to the predicate device. In addition, the two products have very similar technological characteristics and principles of operation. The minor differences in the indications for use statements of the two devices do not change the intended use. In addition, the only notable technological differences between the Caption Interpretation AutoEF and its predicate do not present any new issues of safety or effectiveness because in both cases the key question is whether the EF output of the respective systems is sufficiently accurate and whether the user can review the results to determine whether they are adequate for clinical use. In both cases the systems provide the user with multiple methods to verify the acceptability of image clips used for processing and multiple methods to accept or reject the automated EF estimation. Additionally, the extensive performance testing of the software demonstrates that these differences do not raise any new types of safety or effectiveness questions. Thus, the Caption Interpretation Automated Ejection Fraction Software is substantially equivalent to the predicate device.