InVision Medical Technology Corporation
Golnaz Moeini
Regulatory and Strategy Consultant
9702 Cisco St.
Los Angeles, CA 90034

April 25, 2024

Re: K232331
Trade/Device Name: InVision Precision LVEF (LVEF)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 27, 2024
Received: March 27, 2024

Dear Golnaz Moeini:

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.

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.

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,

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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)*
K232331

Device Name
InVision Precision LVEF (LVEF)

Indications for Use *(Describe)*
In Vision Precision LVEF is used to process previously acquired trans thoracic cardiac ultrasound images, store images, and manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM compliant PACS system to provide an automated estimation of LVEF. This measurement can be used to assist the clinician in a cardiac evaluation. In Vision Precision is indicated for use in patients 22 years and older by sonographers and physicians evaluating cardiac ultrasound.

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

Correspondent Information

InVision Medical Technology Corporation
% Golnaz Moeini
MedEdge Consulting
Email: golnaz.moeini@gmail.com
Phone: (408) 504-3187
Date prepared: March 27, 2024

Device

Proprietary name:	InVision Precision LVEF (LVEF)
Common name:	InVision Precision
Classification name:	Medical image management and processing system
Regulation:	21 CFR 892.2050
Regulatory class:	II
Product code:	QIH Automated Radiological Image Processing Software

Predicate Device

Caption Interpretation Automated Ejection Fraction, K210747.

Device Description

InVision Precision LVEF is a software as a medical device (SaMD), manufactured by InVision Medical Technology Corporation, intended as an aid in diagnostic review and analysis of echocardiographic data, including the evaluation of left ventricular ejection fraction (LVEF) in cardiovascular ultrasound images in DICOM format.

The software interfaces with data files uploaded to a PACS by any ultrasound or data collection equipment. It selects a set of echocardiogram videos of the correct view and generates semi-automatic segmentations of the left ventricle using a machine learning algorithm to form the basis for the calculator of the LVEF output. The analysis results are visualized by the clinician's integrated image view application as adjustable annotations. The user has the option to modify the semi-automatic segmentations suggested by the software. The EF calculation is updated in real-time with the user's modification of the segmentation. A cardiologist can adjust the annotations and the downstream measurement of LVEF prior to finalization.

Intended Use/ Indications for Use

InVision Precision LVEF is used to process previously acquired transthoracic cardiac ultrasound images, store images, and manipulate and make measurements on images using an ultrasound device, personal computer, or a compatible DICOM-compliant PACS system to provide an automated estimation of LVEF. This measurement can be used to assist the clinician in a cardiac evaluation. InVision Precision is indicated for use in patients 22 years and older by sonographers and physicians evaluating cardiac ultrasound.

Summary of Technological Characteristics

A comparison of technological similarities and differences between the subject and predicate devices is as follows:

Feature/ Function	**Subject Device: InVision Precision**	**Predicate Device: Caption Interpretation Automated Ejection Fraction Software K210747**
General Principles of Operation		
Machine Learning-Based Algorithm	Yes	Yes
Operates on DICOM clips	Yes	Yes

Feature/ Function	Subject Device: InVision Precision	Predicate Device: Caption Interpretation Automated Ejection Fraction Software K210747
Automation level	Semi automated	Fully automated
Automated View Selection	Yes	Yes
Views for EF Calculation	Single view or Biplane	Single view or Biplane
Automated Ejection Fraction Calculation	Yes	Yes
Ejection Fraction reported	Numerical estimate	Numerical estimate
User Interface	Uses the interface of approved PACS system	Includes own user interface
Quantitative feedback to enable clinician to assess EF calculation	Adjustable annotation	Confidence Metric
EF result shown with video clip	Yes, with adjustable annotation	Yes
User confirmation/ rejection of result	Yes	Yes
Technological Characteristics		
Network Architecture	Spatiotemporal Pooling	Simple Pooling

Both subject and predicate devices have similar technological characteristics and principles of operation. Any differences do not raise new concerns of safety and efficacy.

Performance Data

The InVision Precision software was developed and tested in accordance with InVision Medical Technology'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 as well as Dice score above a set threshold compared to the consensus annotation of three cardiologists.

Extensive algorithm development and software verification and clinical validation testing, assessed the performance of the software's image video clip selection function and performance characteristics of the algorithm, including accuracy and overall functional performance. Images and cases used for verification and validation testing were separate and carefully segregated from training datasets. Non-clinical verification and validation test results established that the device meets its design requirements and intended use.

Machine Learning Performance Evaluation Summary

A retrospective, multicenter study was designed to evaluate the capability of the Precision machine learning model in calculating LVEF against ground truth. A variety of imaging equipment manufacturers included Philips, GE and Siemens were used for the input data. The average RMSD (Root Mean Square Deviation) for the device's biplane view was around 6.06, for A4C view was 6.17, for A2C view was 7.12. The Dice score for A4C segmentation was 0.89 and for A2C segmentation was 0.90. Data analysis of subgroups included race/ ethnicity, age, gender, BMI, imaging site and equipment, and ejection fraction values. The Precision device met all endpoints.

Conclusions

Performance testing demonstrated that the InVision Precision software performs as expected and in a manner that is substantially equivalent to the predicate device. The InVision Precision software has the same intended use, and similar indications for use, principles of operation and technological characteristics as the predicate device. The

differences do not raise new concerns of safety and effectiveness, therefore the InVision Precision software is substantially equivalent to the predicate device.