May 21, 2025

InVision Medical Technology Corporation
Golnaz Moeini
Medical Device and Regulatory Consultant
9702 Cisco Street
Los Angeles, California 90034

Re: K243866
Trade/Device Name: InVision Precision Cardiac Amyloid
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator

Regulatory Class: Class II
Product Code: SDJ
Dated: April 15, 2025
Received: April 16, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243866

Device Name

InVision Precision Cardiac Amyloid

Indications for Use *(Describe)*

InVision Precision Cardiac Amyloid is an automated machine learning-based decision support system, indicated as a screening tool for adult patients aged 65 years and over undergoing cardiovascular assessment using echocardiography.

When utilized by an interpreting physician, this device provides information alerting the physician for referral to confirmatory investigations.

InVision Precision Cardiac Amyloid is indicated in adult populations over 65 years of age. Patient management decisions should not be made solely on the results of the InVision Precision Cardiac Amyloid.

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

Submitter

InVision Medical Technology Corporation
9702 Cisco St. Los Angeles, CA 90034

Contact person: Golnaz Moeini, Medical Device and Regulatory Consultant
Email: golnaz.moeini@gmail.com
Phone: 408-504-3187
Date prepared: April 11, 2025

Subject Device

Proprietary name:	InVision Precision Cardiac Amyloid
Common name:	InVision Precision Cardiac Amyloid
Regulation:	21 CFR 870.2200; Adjunctive cardiovascular status indicator.
Regulatory class:	II
Product code:	SDJ

Predicate Device

Proprietary name:	Ultromics EchoGo Amyloidosis (K240860)

Device Description

The InVision Precision Cardiac Amyloid (InVision PCA) is a Software as a Medical Device (SaMD) machine-learning screening algorithm to identify high suspicion of cardiac amyloidosis from routinely obtained echocardiogram videos. The device assists clinicians in the diagnosis of cardiac amyloidosis.

The InVision PCA algorithm uses a machine learning process to identify the presence of cardiac amyloidosis. The device inputs images and videos from echocardiogram studies, and it outputs a report suggestive or not suggestive of cardiac amyloidosis. The device has no physical form and is installed as a third-party application to an institution's PACS system.

Intended Use

InVision Precision Cardiac Amyloid is intended to provide adjunctive information on a patient's cardiovascular condition (diagnostic aid for cardiac amyloidosis).

Indications for Use

InVision Precision Cardiac Amyloid is an automated machine learning-based decision support system, indicated as a screening tool for adult patients aged 65 years and over undergoing cardiovascular assessment using echocardiography.

When utilized by an interpreting physician, this device provides information alerting the physician for referral to confirmatory investigations.

InVision Precision Cardiac Amyloid is indicated in adult populations over 65 years of age. Patient management decisions should not be made solely on the results of the InVision Precision Cardiac Amyloid.

Summary of Technological Characteristics

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

Feature	**Subject Device: InVision Precision Cardiac Amyloid**	**Predicate Device: Ultromics EchoGo Amyloidosis K240860**
Regulation	21 CFR 870.2200	Same
Generic Device Type	Adjunctive cardiovascular status indicator	Same
SaMD	Yes	Same
Indications for Use	InVision Precision Cardiac Amyloid is an automated machine learning-based decision support system, indicated as a screening tool for adult patients aged 65 years and over undergoing cardiovascular assessment using echocardiography.	EchoGo Amyloidosis 1.0 is an automated machine learning-based decision support system, indicated as a screening tool for adult patients over 65 years of age with heart failure undergoing routine cardiovascular assessment using echocardiography.

Feature	Subject Device: InVision Precision Cardiac Amyloid	Predicate Device: Ultromics EchoGo Amyloidosis K240860
	When utilized by an interpreting physician, this device provides information alerting the physician for referral to confirmatory investigations. InVision Precision Cardiac Amyloid is indicated in adult populations over 65 years of age. Patient management decisions should not be made solely on the results of the InVision Precision Cardiac Amyloid.	When utilised by an interpreting physician, this device provides information alerting the physician for referral to confirmatory investigations. EchoGo Amyloidosis 1.0 is indicated in adult populations over 65 years of age with heart failure. Patient management decisions should not be made solely on the results of the EchoGo Amyloidosis 1.0 analysis.
Anatomical Site	Cardiovascular	Same
Users	Interpreting clinician	Same
Machine Learning-Based Algorithm	Yes	Same
Operating Platform	Hosted on InVision's platform or third party infrastructure	Same
Interoperability	Compatible with devices compliant with DICOM Standard	Same
Software	Complies with IEC 62304	Same
Risk Management	In accordance with ISO 14971	Same
Cybersecurity	Post-market Management of Cybersecurity in Medical Devices. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. Cybersecurity for Networked Medical Devices Containing Off The-Shelf (OTS) Software: Guidance for Industry.	Same
Human Factors	Human factors validation with intended users	Same
Pre-Clinical	No animal studies were conducted	Same

Feature	Subject Device: InVision Precision Cardiac Amyloid	Predicate Device: Ultromics EchoGo Amyloidosis K240860
Bench Performance Testing	Technical validation, numerical stability, and regression testing.	Same
Clinical Performance Testing	Validated on a validation cohort representative of the intended use population.	Same

Both subject and predicate devices have the same intended use, similar principles of operations, and technological characteristics. Any differences do not raise different questions of safety and effectiveness.

Performance Data

The InVision PCA 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 were conducted to establish the substantial equivalence of the subject device to the predicate. Software verification and validation were conducted in accordance with IEC 62304 - Medical device software – Software life cycle process. The testing demonstrated that software requirements were properly implemented and that the software functions as intended.

The ML model performance validation study was conducted using a total of 1221 unique echocardiogram studies that fulfilled the inclusion and exclusion criteria. The data were selected from three geographically different U.S. sites. The ratio of cardiac amyloidosis cases to non-suspicious non-CA control cases was 1:2. The study compared the device's performance in analyzing previously acquired transthoracic cardiac ultrasound images and identifying cases of Cardiac Amyloidosis compared to confirmatory reference data, such as diagnostic imaging or pathology. The validation study met all its predefined endpoints, demonstrating a sensitivity of 0.607 and a specificity of 0.990. Subgroup analysis was performed across age, gender, BMI, race/ethnicity, CA type, sites, and imaging manufacturers. The device successfully passed the acceptance criteria across all subgroups.

PPV and NPV at various prevalences based on the device's sensitivity (Se) and specificity (Sp).

	Se=60.7% Sp=99.0% (Actual)	
Prevalence	PPV	NPV
0.5%	0.237	0.998
1%	0.384	0.996
2%	0.558	0.992
3%	0.656	0.988
5%	0.765	0.980

Additionally, a human factors validation was conducted to evaluate users can safely and effectively interact with the device. The HF validation consisted of intended users (16 non-cardiologists and 15 cardiologists) and was conducted under simulated-use conditions in the United States. The HF validation concluded that all users were able to comprehend the output report of the device, and the existing use-related errors have been mitigated as far as possible.

Cybersecurity testing - including Dynamic Code Analysis, Vulnerability Scanning, Fuzz Testing, and Penetration Testing - was conducted to evaluate the security of the device. There were no vulnerabilities identified, demonstrating that the InVision PCA's cybersecurity controls are effective and that there are no new cybersecurity-related risks for the InVision PCA.

Conclusions

Performance testing demonstrated InVision Precision Cardiac Amyloid performs as expected and in a manner that is substantially equivalent to the predicate device. InVision PCA 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, InVision Precision Cardiac Amyloid is substantially equivalent to the predicate device.