June 8, 2026

Pathwai, Inc.
Jeffrey Ruhl
Chief of Staff
189 W 89th St.
Apt. 6e
New York, New York 10024

Re: K260332
Trade/Device Name: EchoNext
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: QXO, QYE, SIK, SII, SIJ, SAT
Dated: June 3, 2026
Received: June 3, 2026

Dear Jeffrey Ruhl:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260332

Please provide the device trade name(s).

EchoNext

Please provide your Indications for Use below.

EchoNext is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG (electrocardiogram) made on compatible ECG devices.

EchoNext is capable of analyzing the ECG, detecting signs associated with structural heart disease (SHD), and allowing the user to view the ECG and analysis results. When evidence of SHD is detected, the device additionally may detect six sub-labels, which are specific forms of SHD. EchoNext is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older.

EchoNext is not intended for use on patients with implanted pacemakers. EchoNext is limited to analysis of ECG data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. EchoNext identifies patients for further SHD follow-up and is not intended to replace the current standard of care methods for diagnosis of SHD. The results of the device are not intended to rule-out SHD follow-up.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitter

Applicant	Pathwai, Inc. 169 Madison Avenue, STE 31277, New York, NY 10016
Contact Person	Pierre Elias, MD Chief Executive officer pierre@pathwaylabs.com
Date Prepared	June 8, 2026

Subject Device

Trade/ Device Name:	EchoNext
Regulation Number:	21 CFR 870.2380
Regulation Name:	Cardiovascular machine learning-based notification software
Regulatory Class:	II
Product Code:	QXO, QYE, SAT, SII, SIJ, SIK

Predicate Device

Trade / Device Name:	Viz HCM (DEN230003)

Device Description

EchoNext is a software-as-a-medical-device (SaMD) intended to assist clinicians by analyzing standard resting 12-lead electrocardiogram (ECG) recordings to identify patients who may be suspected of having structural heart disease (SHD) and who may benefit from further diagnostic evaluation.

EchoNext functions by processing digital 12-lead ECG waveform data using a machine-learning algorithm based on deep neural network techniques. The scientific basis of the device is the established relationship between subtle electrical patterns present in ECG signals and underlying structural abnormalities of the heart, such as abnormalities of cardiac chambers, walls, or valves.

The device evaluates ECG waveform data in combination with basic demographic inputs to generate a notification indicating whether the ECG demonstrates patterns associated with suspicion of structural heart disease. When SHD is suspected, the device may also provide informational indicators corresponding to affected cardiac structures. The potential outputs of EchoNext and their product codes are:

Output	Product code
SHD: Structural Heart Disease	QXO
LVEF: Left Ventricular Ejection Fraction	QYE
LVH: Left Ventricular Hypertrophy	SIK
AS: Aortic Stenosis	SII
Valvular Regurgitation	SIJ
RVEF: Right Ventricular Ejection Fraction	QYE
PH: Pulmonary Hypertension	SAT

Intended Use / Indications for Use

EchoNext is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG (electrocardiogram) made on compatible ECG devices.

EchoNext is capable of analyzing the ECG, detecting signs associated with structural heart disease (SHD), and allowing the user to view the ECG and analysis results. When evidence of SHD is detected, the device additionally may detect six sub-labels, which are specific forms of SHD. EchoNext is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older.

EchoNext is not intended for use on patients with implanted pacemakers. EchoNext is limited to analysis of ECG data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. EchoNext identifies patients for further SHD follow-up and is not intended to replace the current standard of care methods for diagnosis of SHD. The results of the device are not intended to rule-out SHD follow-up.

Summary of Technological Characteristics

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

Characteristic	Subject Device: Pathwai EchoNext	Predicate Device: Viz.ai HCM Module (DEN230003)
Regulation Number	21 CFR 870.2380	Same
Regulation Name	Cardiovascular Machine Learning Based Notification Software	Same
Product Codes	QXO, QYE, SAT, SII, SIJ, SIK	QXO
SaMD	Yes	Same
Indications for Use	EchoNext is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG made on compatible ECG devices. EchoNext is capable of analyzing the ECG, detecting signs associated with structural heart disease (SHD), and allowing the user to view the ECG and analysis results. EchoNext is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older. EchoNext is not intended for use on patients with implanted pacemakers. EchoNext is limited to analysis of ECG data and should not be used in lieu of full patient evaluation or relied upon to make or confirm diagnosis. EchoNext identifies patients for further SHD follow-up and is not intended to replace the current standard of care methods for diagnosis of SHD. The results of the device are not intended to rule-out SHD follow-up.	Viz HCM is intended to be used in parallel to the standard of care to analyze recordings of 12-lead ECG made on compatible ECG devices. Viz HCM is capable of analyzing the ECG, detecting signs associated with hypertrophic cardiomyopathy (HCM), and allowing the user to view the ECG and analysis results. Viz HCM is indicated for use on 12-lead ECG recordings collected from patients 18 years of age or older. Viz HCM is not intended for use on patients with implanted pacemakers. Viz HCM is limited to analysis of ECG data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz HCM identifies patients for further HCM follow-up and does not replace the current standard of care methods for diagnosis of HCM. The results of the device are not intended to rule-out HCM follow-up.
Clinical Specialty	Cardiovascular	Same
Rx/OTC	Rx	Same
Patient Population	≥18 years	Same
Use with Pacemakers?	No	Same

Characteristic	Subject Device: Pathwai EchoNext	Predicate Device: Viz.ai HCM Module (DEN230003)
Locked Machine Learning Model	Yes	Same
Input	12-lead ECG	Same
Output (Non-Diagnostic Notification)	Binary notification **Primary Indicator:** SHD: Structural Heart Disease **Sub-Labels:** • AS: Aortic Stenosis (moderate or greater) • Valvular Regurgitation (moderate or greater): Aortic Regurgitation, Mitral Regurgitation, Pulmonary Regurgitation, Tricuspid Regurgitation • LVH: Left Ventricular Hypertrophy (severe LVH) • LVEF: Left Ventricular Ejection Fraction (≤ 45%) • RVEF: Right Ventricular Ejection Fraction (moderate or greater dysfunction) • PH: Pulmonary Hypertension (PASP ≥ 45mmHg or TR max velocity ≥ 3.2 m/s)	Binary notification (HCM flag)
Built-In View	No	Yes

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.

Summary of Nonclinical Tests

The following nonclinical tests were conducted to support the safety and effectiveness of EchoNext.

- Software Verification and Validation: SW V&V activities included Unit Testing, Integration and System-level testing. All software requirements successfully met their predefined acceptance criteria.
- Cybersecurity Testing: Cybersecurity testing - including Static and Dynamic Code Analysis, Fuzz Testing, and Penetration testing - was successfully conducted, demonstrating cybersecurity risks have been properly mitigated.
- Human Factors Validation - Human factors testing with 15 participants representative of the intended user population was successfully conducted, demonstrating use-related risks have been properly mitigated.

Summary of Clinical Performance Data

EchoNext was validated based on a retrospective, multicenter evaluation designed to assess performance in a real-world clinical setting. The analysis uses a large dataset comprising 102,219 unique consecutive patients, with one ECG per patient, drawn from four geographically distinct health systems in the United States and Canada. These sites span academic and community hospitals and represent urban, suburban, and diverse patient populations, supporting evaluation across varied care environments, demographic groups, and disease prevalence patterns. The dataset was assembled to maximize geographic and clinical diversity.

Clinical ground truth was established using transthoracic echocardiography, which serves as the diagnostic reference standard for structural heart disease. Echocardiograms were interpreted by board-certified cardiologists using FDA-cleared systems, and finalized reports were used to extract structured measurements and diagnostic assessments. From these reports, a composite structural heart disease label was derived, along with multiple clinically relevant sub-labels, including left and right ventricular systolic dysfunction, severe left ventricular hypertrophy, moderate or greater valvular regurgitation, moderate or greater aortic stenosis, and moderate or greater pulmonary hypertension. Sub-labels were assigned using guideline-based thresholds, and multiple sub-labels could be present for a single patient.

Sub-group analyses included stratifications of device performance by age, sex, ECG manufacturer, comorbidity, race and ethnicity, and baseline ECG to index TTE. In all circumstances, EchoNext met its acceptance criteria, demonstrating clinical acceptability of device performance. Additional testing completed for the EchoNext device includes software verification and validation, human factors validation, and cybersecurity testing.

Study Design and Patient Population

The external validation dataset comprised 102,219 unique patients drawn from four geographically and demographically distinct health systems in the United States and Canada. Sites were selected to maximize geographic, demographic, and clinical diversity, spanning academic and community hospitals in urban, suburban, and rural settings. The median patient age was 66.3 years (IQR 57–79); 52.0% were male.

Race/ethnicity: 41.4% White, 17.4% Asian, 10.8% Hispanic, and 6.1% Black. SHD prevalence was 34.8% (35,548 / 102,219).

Performance Analysis

EchoNext was validated in an external, prospectively enrolled cohort of 102,219 patients across four independent clinical sites. Patients who had a clinically ordered 12-lead ECG and a transthoracic echocardiogram within 30 days were included. Ground truth for each condition was established by board-certified cardiologists interpreting the echocardiogram report, blinded to ECG findings.

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with 95% confidence intervals were computed across the full external validation cohort for both the composite structural heart disease (SHD) output and each of the six sub-label outputs. Pre-specified acceptance criteria were defined separately for sensitivity and specificity for each output prior to testing.

EchoNext met all pre-specified acceptance criteria across the composite SHD output and all six sub-labels. EchoNext achieved a sensitivity of 73.7% (95% confidence interval: 73.2-74.1%) and a specificity of 75.2% (74.9-75.5%) in detecting SHD in the external validation. **Table 1 shows performance for EchoNext and each sub-label.**

Table 1: Performance Characteristics of EchoNext in performance study dataset. The sensitivity, specificity, PPV, and NPV of EchoNext in detecting SHD and each sub-label

	Sensitivity	Specificity	PPV	NPV	Prevalence
SHD	73.7 (73.2-74.1)	75.2 (74.9-75.5)	61.6 (61.2-62.1)	84.6 (84.3-84.9)	34.8%
Left Ventricular Systolic Dysfunction	80.1 (79.4-80.9)	80.4 (80.1-80.6)	34.8 (34.2-35.3)	97.0 (96.9-97.2)	11.3%
Right Ventricular Systolic Dysfunction	76.8 (75.3-78.3)	82.5 (82.3-82.7)	12.1 (11.6-12.5)	99.2 (99.1-99.2)	3.0%
Aortic Stenosis	54.9 (53.4-56.3)	80.1 (79.8-80.3)	11.8 (11.4-12.3)	97.4 (97.3-97.5)	4.5%
Valvular Regurgitation	58.2 (57.5-59.0)	83.9 (83.7-84.2)	42.2 (41.6-42.9)	91.2 (91.0-91.4)	16.4%
Pulmonary Hypertension	64.1 (63.1-65.1)	81.1 (80.8-81.4)	25.3 (24.8-25.9)	95.9 (95.8-96.0)	8.9%
Left Ventricular Hypertrophy	48.2 (46.9-49.4)	81.3 (81.1-81.6)	14.2 (13.8-14.7)	96.2 (96.0-96.3)	5.9%

We additionally estimated how PPV and NPV would change at different prevalences for some sub-labels. For valvular regurgitation, the PPV and NPV would be 24.4% and 95.7% at a prevalence of 8.2%, and 16.0% and 97.4% at a prevalence of 5.0%. For pulmonary hypertension, the PPV and NPV would be 13.2% and 98.0% at a prevalence of 4.3%, and 9.5% and 98.6% at a prevalence of 3.0%.

Conclusions

EchoNext performs as expected and in a manner that is substantially equivalent to the predicate device. EchoNext 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, EchoNext is substantially equivalent to the predicate device.

Nonclinical testing, including software verification and validation (101/101 test cases passing), human factors engineering validation (zero use errors or close calls across 15 participants), and cybersecurity testing (no vulnerabilities identified) demonstrated that EchoNext meets applicable safety and performance requirements.

Clinical performance testing conducted on 102,219 patients across four geographically and demographically diverse health systems demonstrated that EchoNext met all pre-specified acceptance criteria for the composite SHD label and all six sub-labels, with consistent performance across all evaluated subgroups. Therefore, EchoNext is substantially equivalent to the predicate device.