March 27, 2026

GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
Tahir Rizvi
Sr. Director of Regulatory Affairs
3200 N Grandview Blvd.
Waukesha, Wisconsin 53188

Re: K254161
Trade/Device Name: Automated Aortic Stenosis Software (AutoAS)
Regulation Number: 21 CFR 892.2060
Regulation Name: Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulatory Class: Class II
Product Code: POK
Dated: February 27, 2026
Received: February 27, 2026

Dear Tahir Rizvi:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

for

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254161

Device Name
Automated Aortic Stenosis Software (AutoAS)

Indications for Use *(Describe)*
AutoAS is a software application intended to assist medical professionals in the assessment of moderate/severe aortic stenosis (AS). The software uses an artificial intelligence (AI) algorithm to process previously acquired two-dimensional transthoracic echocardiography (2D-TTE) images to provide a suggestion of moderate/severe aortic stenosis along with an associated confidence metric that can be a diagnostic aid to a physician in a point of care or similar setting in determining if further evaluation is needed, including whether a full echocardiogram (2D, Doppler) needs to be performed.

The results of AutoAS are not intended to be used on a stand-alone basis for clinical decision making and are not intended to supplement or replace a full echocardiographic examination. AutoAS results, along with the obtained ultrasound images, must be reviewed by a qualified physician. The AutoAS product is not intended to be used on patients who have prosthetic valves and/or have had prior valve repair or replacement.

AutoAS software is indicated for use in adult patients and is intended to be an accessory to compatible ultrasound systems in environments where healthcare is provided.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

510(k) Number	K254161
Date	March 26, 2026
Submitter	GE Medical Systems Ultrasound & Primary Care Diagnostics LLC 3200 N Grandview Blvd. Waukesha, WI, 53188, United States
Primary Contact Person	Zahra Ghanian Email: zahra.ghanian@gehealthcare.com Phone: +1 (385)866-0594
Secondary Contact Person	Tahir Rizvi, Sr. Director of Regulatory Affairs Email: Tahir.rizvi@gehealthcare.com Phone: +1 (781)290-6264
Device Trade Name	Automated Aortic Stenosis Software
Common/Usual Name	AutoAS
Classification Name	892.2060 - Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulatory Class	Class II
Product Code	POK
Predicate Device	EchoGo Pro (K201555) Ultromics Ltd

1. DEVICE DESCRIPTION

Automated Aortic Stenosis Software (AutoAS) is a breakthrough[1] software product that assesses the presence and severity of aortic stenosis (AS) in B-mode cardiac ultrasound scans. The software can be integrated with a compatible ultrasound device in a headless manner. The AutoAS software is intended to be an accessory to compatible ultrasound systems. The AutoAS software is intended for use in adult patients undergoing transthoracic cardiac ultrasound examinations in whom assessment for aortic stenosis (AS) is clinically relevant. The indicated population includes patients who are being evaluated for the presence or likelihood of moderate to severe aortic stenosis as part of a routine or targeted echocardiographic study.

AutoAS processes relevant ultrasound images acquired from a concurrent and/or previously acquired ultrasound exam, employing advanced algorithms to generate AS predictions and supporting outputs for the user. The AutoAS software operates on B-mode transthoracic cardiac ultrasound images acquired during a standard ultrasound examination using a compatible GE HealthCare ultrasound system. The reading protocol is designed to ensure that AutoAS outputs are used as adjunctive information and are interpreted within the context of a comprehensive clinical and echocardiographic evaluation by a qualified physician. The AS prediction, severity, and supporting outputs are summarized as a report that is available after the exam for the user to review. The report can also be exported to an archive with the ultrasound images ensuring seamless integration with the patient's record and facilitating downstream clinical workflows.

The software's algorithms process specific views obtained during an ultrasound study. These views may include the parasternal long axis (PLAX), parasternal short axis at the aortic valve level (PSAX-AV), and apical five-chamber (AP5). The AS predictions come in the form of a severity prediction: 1) Suggestive of moderate to severe AS or 2) Not suggestive of moderate to severe AS with associated information on the confidence of the algorithm's prediction.

The AutoAS results along with ultrasound images must be reviewed by a qualified physician as the AutoAS software does not diagnose Aortic Stenosis (AS) but rather indicates the likelihood of AS. Interpretation of AutoAS results must be performed by a qualified physician with training and experience in cardiac ultrasound and echocardiographic interpretation. The results of AutoAS are not intended to be used on a stand-alone basis for clinical decision making and are not intended to supplement or replace a full echocardiographic examination. The physician must review the AutoAS outputs in conjunction with the underlying ultrasound images and relevant clinical information. The user is responsible for determining the clinical relevance of the AutoAS findings and for integrating the software outputs into the overall diagnostic impression.

2. INTENDED USE/INDICATIONS FOR USE

AutoAS is a software application intended to assist medical professionals in the assessment of moderate/severe aortic stenosis (AS). The software uses an artificial intelligence (AI) algorithm to process previously acquired two-dimensional transthoracic echocardiography (2D-TTE) images to provide a suggestion of moderate/severe aortic stenosis along with an associated confidence metric that can be a

[1] AutoAS received Breakthrough Device designation from the U.S. FDA

diagnostic aid to a physician in a point of care or similar setting in determining if further evaluation is needed, including whether a full echocardiogram (2D, Doppler) needs to be performed.

The results of AutoAS are not intended to be used on a stand-alone basis for clinical decision making and are not intended to supplement or replace a full echocardiographic examination. AutoAS results, along with the obtained ultrasound images, must be reviewed by a qualified physician. The AutoAS product is not intended to be used on patients who have prosthetic valves and/or have had prior valve repair or replacement.

AutoAS software is indicated for use in adult patients and is intended to be an accessory to compatible ultrasound systems in environments where healthcare is provided.

3. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Automated Aortic Stenosis Software (AutoAS) has similar intended use and similar indications, technological characteristics, and principles of operation as the previously cleared EchoGo Pro device manufactured by Ultromics Ltd. A substantial equivalence chart comparing the similarities and differences between the AutoAS, and EchoGo Pro is provided at the end of the summary document below (Table 2). The minor differences in the technological characteristics do not raise different questions of safety or efficacy. Software verification, validation and performance data demonstrates that the AutoAS is substantially equivalent to its predicate device.

4. NONCLINICAL TESTING

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance "Content of Premarket Submission for Device Software Functions" (issued June 14, 2023) for devices classified as "Basic" Level of Concern as defined in the Guidance. AutoAS was developed and tested in accordance with GE HealthCare's Quality Management System. Software documentation generated as part of the design process included:

- Software/Firmware Description
- Risk Management File
- Software Requirements Specifications
- System and Software Architecture
- Software Lifecycle Process Description
- Software Testing as Part of Verification and Validation
- Software Version/Revision Level History
- Unresolved Software Anomalies
- Cybersecurity

In addition to software verification and validation testing, standalone non-clinical testing of the algorithm components of AutoAS was performed. A summary is provided below:

Test	Purpose	Result
Confidence Metric	AutoAS produces a confidence metric, also known simply as "confidence", whenever it makes a prediction. With this metric, the algorithm aims to highly correlate with the true probability of a successful binary classification of the severity of aortic stenosis.	Testing demonstrated a statistically monotonically increasing relationship between the confidence value and the probability of accurately detecting whether moderate / severe aortic stenosis was present.
Clip Annotator	Before analysis, AutoAS evaluates each clip with a clip annotator. The function of the clip annotator is to confirm if the clip is B-mode and part of "valid" views (such as PLAX, PSAX-AV etc.) and rejects any other views.	Testing demonstrated both a positive predictive value (PPV) and Sensitivity of 100% (95% CI: (98.5%, 100.0%)) across all view types (i.e., PLAX, AP5, PSAX-AV, and all other views) when classifying the B-mode image. For any image that was classified as B-mode, the ability to accurately classify the view was also tested, and the verification test results revealed a PPV of at least 97.1% (95% CI: (94.2%, 98.8%)) and a Sensitivity of at least 87.5% (95% CI: (83.1%, 91.2%)) across all view types.
Heart Rate Estimation	AutoAS has the ability to predict a patient's heart period by looking solely at the video clip. The estimated heart rate is not reported to the user and is used only internally to the software.	The verification testing demonstrated a statistically significantly lesser MAD / MAE than the established benchmark for all views (AP5, PLAX, and PSAX). Based on these results, there were no clinically significant differences between the estimated heart rates by the software and the reference measurements.

5. CLINICAL PERFORMANCE TESTING

Clinical testing to evaluate the performance of the AutoAS consisted of two studies:

- **Standalone Performance Assessment**, comparing the performance of the software against a panel of level III cardiologists independently reading full echocardiography studies
- **Clinical Performance Assessment** (i.e., multi-case multi reader performance study), in which the performance of reading clinicians was assessed with and without the help of AutoAS software

Standalone Performance Assessment:

A validation dataset was retrospectively obtained consisting of a total 401 studies from 401 unique patients from four different U.S. institutions. The validation dataset consisted of echocardiographic studies from multiple ultrasound models from two different ultrasound manufacturers:

- GE Healthcare: "Vivid E95", "Vivid E9", "Vivid i", and "Vscan Air SL"
- Philips Healthcare: "iE33", "CX50", "EPIQ 5C", "EPIQ CVx", and "EPIQ 7C

A full read was performed to establish the reference standard, with each of the studies assessed independently by each of three (3) level-III echocardiographers for AS severity according to Aortic Valve Area (AVA) per clinical guidelines from the American Society of Echocardiography (ASE).

Each echocardiographer was blinded to the interpretation by the other two echocardiographers and blinded to the original AS interpretation result from the original study. Each echocardiographer had access to complete study data and imaging as available from the echocardiographic study. The reference standard was the majority vote of the 3 echocardiographers (also known as the statistical mode).

Results:

The standalone assessment findings demonstrated strong overall performance; Area Under the ROC Curve, 93.2% [95% CI: 90.5% - 95.6%] which is statistically significantly greater than the predefined performance target. Specificity of 92.4% [95% CI: 86.3% - 98.4%] and sensitivity of 75.2% [95% CI: 67.4% - 83.0%] were observed, on par with original reading cardiologists when compared to the same reference panel). Consistency was noted in the performance metrics across relevant sub-group parameters such as the age of the subject, BMI, gender, device manufacturer, and the site location used during the examination.

Table 1. Consistency of performance metrics across relevant sub-group parameters

Area under the ROC Curve		
Parameter	**Sample Size**	**Point Estimate**
Age (Years)		
< 65	104	0.964
≥ 65	278	0.908
BMI		
< 25	121	0.944
25 - 30	126	0.903
≥ 30	135	0.959
Gender		
Female	187	0.947
Male	195	0.920
Site Location		
Site: Group #1	218	0.922
Site: Group #2	116	0.945
Site: Group #3	48	0.953

Sensitivity		
Parameter	**Sample Size**	**Point Estimate**
Age (Years)		
< 65	45	0.711
≥ 65	193	0.762
BMI		
< 25	86	0.733
25 - 30	73	0.740
≥ 30	79	0.785
Gender		
Female	113	0.726
Male	125	0.776
Site Location		
Site: Group #1	140	0.757
Site: Group #2	73	0.699
Site: Group #3	25	0.880

Specificity		
Parameter	**Sample Size**	**Point Estimate**
Age (Years)		
< 65	59	0.983
≥ 65	85	0.882
BMI		
< 25	35	1.000
25 - 30	53	0.849
≥ 30	56	0.946
Gender		
Female	74	0.973

Male	70	0.871
Site Location		
Site: Group #1	78	0.885
Site: Group #2	43	1.000
Site: Group #3	23	0.913

Clinical Performance Assessment:

A multi-reader, multi-case (MRMC) study was conducted to assess the diagnostic performance of AutoAS, with five (5) expert echocardiography readers reviewing all studies with AutoAS (aided) and without AutoAS (unaided). A subset of validation data from the standalone performance assessment was used for the clinical performance assessment. This dataset consisted of 220 unique studies across 220 unique patients from three different U.S. institutions. A randomized crossover approach was utilized in which readers were randomly assigned to the unaided or aided arm and then were switched to the other arm after a one (1) month wash-out period.

Results:

A statistically significant improvement in sensitivity was observed for the "Aided" readers compared to the "Unaided" readers (+ 5.5%, 95% CI: (1.5%, 9.5%)), while maintaining comparable specificity (0.897 vs. 0.900). Furthermore, when comparing the diagnostic performance of the two reader groups, the critical region of the ROC curve revealed superiority for the "Aided" group with an 8.9% [95% CI: 1.2%, 20.5%] difference in partial AUROC. In addition, aided readers demonstrated higher inter-rater agreement (89.0%) than unaided readers (81.9%), comparable to the reference standard (88.7%), reflecting improved reader consistency and diagnostic performance.

6. CONCLUSION

AutoAS is substantially equivalent to EchoGo Pro, cleared under K201555. Both devices share a similar intended use, indications, technological characteristics, and principles of operation. Both devices are software-based medical tools employing machine-learning algorithms to aid in the assessment of heart conditions, although they focus on different clinical applications. AutoAS targets aortic stenosis (AS), while EchoGo Pro assesses coronary artery disease (CAD). Despite minor differences in specific technological features and conditions evaluated, these distinctions do not affect its safety and effectiveness when used as labeled. Extensive performance testing has demonstrated that the AutoAS is substantially equivalent to its predicate device.

Table 2: Substantial Equivalence Comparison Chart

Category	Subject Device	Predicate Device	Discussion
Manufacturer	GE HealthCare	Ultromics Ltd.	N/A
Device	AutoAS	EchoGo Pro (K201555)	N/A
Intended Use/Indications for Use	AutoAS is a software application intended to assist medical professionals in the assessment of moderate/severe aortic stenosis (AS). The software uses an artificial intelligence (AI) algorithm to process previously acquired two-dimensional transthoracic echocardiography (2D-TTE) images to provide a suggestion of moderate/severe aortic stenosis along with an associated confidence metric that can be a diagnostic aid to a physician in a point of care or similar setting in determining if further evaluation is needed, including whether a full echocardiogram (2D, Doppler) needs to be performed. The results of AutoAS are not intended to be used on a stand-alone basis for clinical decision making and are not intended to supplement or replace a full echocardiographic examination. AutoAS results, along with the obtained ultrasound images, must be reviewed by a qualified physician.	EchoGo Pro v1.0.2 is a machine learning-based decision support system, indicated as an adjunct to diagnostic stress echocardiography for patients undergoing assessment for coronary artery disease (CAD). When utilized by an interpreting physician, this device provides information that may be useful in rendering an accurate diagnosis. Patient management decisions should not be made solely on the results of the EchoGo Pro v1.0.2 analysis. EchoGo Pro v1.0.2 is to be used with stress echo exam protocols that contain A2C, A4C, and mid-ventricular short-axis views at rest and at peak stress. EchoGo Pro v1.0.2 is not intended for the assessment of mild or moderate myocardial ischemia, or localization of coronary artery disease, or for the assessment of myocardial perfusion, myocardial viability, or valve disease. Limitations: EchoGo Pro v1.0.2 has not been validated on patients who underwent previous coronary artery bypass graft (CABG) surgery.	Similar. Both devices are intended to be used as diagnostic aids for cardiac evaluation. Both devices specify in the indications for use that patient management should not be driven solely by the output of the devices. and both devices are intended to be used by the reading physician as part of patient evaluation i.e., obtained images must be formally interpreted and reported by a qualified physician. Therefore, both devices are not intended to replace the skill and judgment of a qualified medical practitioner. There is a minor difference in the specific condition that is being automatically detected between the devices, with the predicate assessing coronary artery disease (CAD) and the subject device assessing AS; however, both devices are designed to operate within the same anatomical area.

Category	Subject Device	Predicate Device	Discussion
	The AutoAS product is not intended to be used on patients who have prosthetic valves and/or have had prior valve repair or replacement. AutoAS software is indicated for use in adult patients and is intended to be an accessory to compatible ultrasound systems in environments where healthcare is provided.		
Classification Name	Radiological computer-assisted diagnostic software for lesions suspicious of cancer	Radiological computer-assisted diagnostic software for lesions suspicious of cancer	Identical
Product Code	POK	POK	Identical
Regulation Number	21 CFR 892.2060	21 CFR 892.2060	Identical
Modality	Ultrasound (Echocardiography)	Ultrasound (Echocardiography)	Identical
Anatomical Site	Cardiovascular	Cardiovascular	Identical
Clinical Condition	Aortic Stenosis	Coronary Plaques	Similar. Despite minor difference in specific conditions evaluated, this distinction does not raise new safety or efficacy concerns as both clinical conditions are diagnostic in nature in the same anatomical site.
Echocardiogram Views	PLAX, PSAX-AV, AP5	A2C, A4C, Mid-ventricle AX	While the specific image views required differ slightly between the devices, both incorporate quality-control measures to

Category	Subject Device	Predicate Device	Discussion
			ensure sufficient input data and generate user-facing reports to support cardiac evaluations.
Machine-Learning Based Algorithm	Yes	Yes	Substantially equivalent. Both devices utilize deep-learning artificial intelligence as the core technology to provide diagnostic aid to the user in the assessment of heart conditions.
Clinical Output	Two-level (Binary) Output: Suggestive of moderate to severe AS Or Not suggestive of moderate to severe AS Confidence score generated at study-level.	Two-level (Binary) Output: Suggestive of a lower risk of prognostically significant coronary artery disease Or Suggestive of a higher risk of prognostically significant coronary artery disease.	Both devices process ultrasound images to generate a two-level diagnostic output intended to assist medical professionals. The subject device includes a confidence score whereas the predicate device does not. The confidence score indicates how certain the algorithm is in its prediction, based on the clips analyzed. This difference does not raise safety or efficacy concerns because the confidence score is only intended as supporting information but does not replace physician responsibility for diagnosis.
Labelled for Interpreting Physician Read	Yes	Yes	Identical. Both devices do not replace clinical judgment, emphasizing that all exams must

Category	Subject Device	Predicate Device	Discussion
			be reviewed by an interpreting reading physician.