



August 12, 2025

Eko Health, Inc.
Sam Huang
Director of Regulatory Affairs
2100 Powell Street
Suite 300
Emeryville, California 94608

Re: K251494

Trade/Device Name: Eko Foundation Analysis Software with Transformers (EFAST)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC, DPS, MWI
Dated: May 9, 2025
Received: May 15, 2025

Dear Sam Huang:

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,

Diagnosics, and Monitoring Devices

Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251494

Device Name
Eko Foundation Analysis Software with Transformers (EFAST)

Indications for Use (Describe)

The Eko Foundation Analysis Software with Transformers (EFAST) is intended to support healthcare professionals in the evaluation of patients' heart sounds and electrocardiograms (ECGs). The software calculates heart rate, detects the presence of murmurs associated with Structural Heart Disease, and determines murmur timing including the timing of S1, S2 heart sounds. When ECG is available, the software detects the presence of atrial fibrillation and normal sinus rhythm.

The software is intended for use by or under the supervision of a healthcare professional and is not to be used as a sole means of diagnosis. The interpretations of heart sounds and ECG offered by the software are designed to support and not replace the healthcare professional's clinical judgment. The murmur detection is intended for use on both pediatric and adult patients, while the detection of atrial fibrillation is intended for use on adults (> 18 years).

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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K251494

GENERAL INFORMATION

Applicant:

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Contact Person:

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Date Prepared: May 13, 2025

DEVICE INFORMATION

Trade/Proprietary Name: Eko Foundation Analysis Software with Transformers (EFAST)
Regulation number: 21 CFR 870.1875
Device Classification Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC, DPS, MWI

PREDICATE DEVICE

Primary Predicate: Eko Murmur Analysis Software (EMAS, K213794)
Reference Device: Eko Analysis Software (EAS, K192004)

DEVICE DESCRIPTION

Eko Foundation Analysis Software with Transformers (EFAST) is a cloud-based Software as a Medical Device (SaMD) intended to provide clinical decision support to healthcare professionals (HCP) in the evaluation of patients' heart sounds (phonocardiogram, PCG) and electrocardiograms (ECGs). The software employs signal processing techniques and machine learning (Deep Neural Networks) to perform simultaneous analysis of recorded heart sounds and ECG data (when available), and identify the presence of murmurs associated with Structural Heart Disease, and determine murmur timing including the timing of S1, S2 heart sounds. When ECG is available, the software also detects the presence of atrial fibrillation and sinus rhythm.

The software does not identify other arrhythmias. In addition, it calculates the heart rate of the patient.

The EFAST Software accepts input consisting of heart sounds and ECG waveforms recorded using Eko Digital Stethoscopes that are saved in .WAV file format and stored in the Eko Cloud, which utilizes the Amazon Web Services (AWS) Simple Storage Service (S3) for data storage and for easy communication with the EFAST analysis server. When an API Request is sent to the EFAST API, the corresponding recordings (PCG and/or ECG) are accessed by the EFAST software and they are analyzed by the EFAST software components. After analysis, the EFAST software returns a JSON format data structure with the algorithm results, which is saved back to the Eko Cloud and can be displayed on EFAST API integrated target software or devices (e.g. user-facing apps).

The EFAST Software consists of the following algorithm components:

- Heart Sound Signal Quality Classifier: Evaluates whether an audio recording contains heart sounds of sufficient quality for further clinical analysis
- Structural Murmur Classifier: Determines whether a good-quality heart sound recording contains a structural murmur or not
- Heart Sound Timing & Murmur Timing: Determines the timing of S1 and S2 heart sounds and determines whether a structural murmur occurs during the systolic or diastolic phase
- ECG Rhythm Classifier: Analyzes ECG signals and categorizes them into one of four classifications: Sinus Rhythm, Atrial Fibrillation, Unspecified Rhythm, and Poor ECG Signal
- Heart Rate Calculation: Signal processing algorithm that utilizes ECG and PCG to calculate heart rate value in beats per minute

INDICATIONS FOR USE

The Eko Foundation Analysis Software with Transformers (EFAST) is intended to support healthcare professionals in the evaluation of patients' heart sounds and electrocardiograms (ECGs). The software calculates heart rate, detects the presence of murmurs associated with Structural Heart Disease, and determines murmur timing, including the timing of S1, S2 heart sounds. When ECG is available, the software detects the presence of atrial fibrillation and normal sinus rhythm.

The software is intended for use by or under the supervision of a healthcare professional and is not to be used as a sole means of diagnosis. The interpretations of heart sounds and ECG offered by the software are designed to support and not replace the healthcare professional's clinical judgment. The murmur detection is intended for use on both pediatric and adult patients, while the detection of atrial fibrillation is intended for use on adults (> 18 years).

SUBSTANTIAL EQUIVALENCE

The Eko Foundation Analysis Software with Transformers (EFAST) has the same intended use and fundamental technological characteristics as both the predicate (Eko Murmur Analysis Software, EMAS). Differences in ECG analysis, patient population, and technological characteristics do not raise new questions on safety or effectiveness compared to the predicate and reference devices. A substantial equivalence comparison table between the subject device and the predicate device is provided below.

Table 1: Substantial Equivalence Comparison Table

Feature	Subject Device: Eko Foundation Analysis Software with Transformers (EFAST)	Predicate Device: Eko Murmur Analysis Software (EMAS) (K213794)	Reference Device: Eko Analysis Software (EAS) (K192004)
Regulation Number and Name	21 CFR 870.1875 Stethoscope	21 CFR 870.1875 Stethoscope	21 CFR 870.2300 Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Classification Product Code	DQD, DQC, DPS, MWI	DQD, DQC, DPS	MWI, DQD, DPS
Indications for Use	The Eko Foundation Analysis Software with Transformers (EFAST) is intended to support healthcare professionals in the evaluation of patients' heart sounds and electrocardiograms (ECGs). The software calculates heart rate, detects the presence of murmurs associated with Structural Heart Disease, and determines murmur timing including the timing of S1, S2 heart sounds. When ECG is	The Eko Murmur Analysis Software is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms (and ECG signals, when available). The software will automatically detect murmurs that may be present, and the murmur timing and character, including S1, S2, innocent heart murmurs, structural	The Eko Analysis Software is intended to provide support to the physician in the evaluation of patients' heart sounds and ECG's. The software analyzes simultaneous ECG and heart sounds. The software will detect the presence of suspected murmurs in the heart sounds. The software also detects the presence of atrial fibrillation and normal sinus rhythm from the ECG signal. In

Feature	Subject Device: Eko Foundation Analysis Software with Transformers (EFAST)	Predicate Device: Eko Murmur Analysis Software (EMAS) (K213794)	Reference Device: Eko Analysis Software (EAS) (K192004)
	<p>available, the software detects the presence of atrial fibrillation and normal sinus rhythm.</p> <p>The software is intended for use by or under the supervision of a healthcare professional and is not to be used as a sole means of diagnosis. The interpretations of heart sounds and ECG offered by the software are designed to support and not replace the healthcare professional's clinical judgment. The murmur detection is intended for use on both pediatric and adult patients, while the detection of atrial fibrillation is intended for use on adults (> 18 years).</p>	<p>heart murmurs, and the absence of a heart murmur.</p> <p>The Eko Murmur Analysis Software is not intended as a sole means of diagnosis and is for use in environments where healthcare is provided by clinicians. The interpretations of heart sounds offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. The interpretations are not diagnoses. The Eko Murmur Analysis Software is intended for use on pediatric and adult patients.</p>	<p>addition, it calculates certain cardiac time intervals such as heart rate, QRS duration and EMAT. The software does not distinguish between different kinds of murmurs and does not identify other arrhythmias.</p> <p>It is not intended as a sole means of diagnosis. The interpretations of heart sounds and ECG offered by the software are only significant when used in conjunction with physician over-read and is for use on adults (> 18 years).</p>
Prescription / OTC	Prescription Use Only	Prescription Use Only	Prescription Use Only
Patient Population	<p>Murmur detection: Adult and pediatric patients</p> <p>Atrial fibrillation detection: Adults (>18 years) patients</p>	Adult and pediatric patients	Adults (>18 years) patients
Components	Software Only	Software Only	Software Only

Feature	Subject Device: Eko Foundation Analysis Software with Transformers (EFAST)	Predicate Device: Eko Murmur Analysis Software (EMAS) (K213794)	Reference Device: Eko Analysis Software (EAS) (K192004)
Interface	Callable application programming interface (API)	Callable application programming interface (API)	Callable application programming interface (API)
Display	No primary display	No primary display	No primary display
Murmur Detection	Yes	Yes	Yes
Structural Murmur Classification	Yes	Yes	No
Physiological Input Signals	Patients' heart sounds and electrocardiograms (ECGs)	Patients' heart sounds and electrocardiograms (ECGs, when available)	Patients' heart sounds and electrocardiograms (ECGs)
Heart Sound Signal Quality Classification	Yes	Yes	Yes
Heart Sound Timing and Murmur Timing	S1 and S2 Systolic vs. Diastolic Murmur characterization	S1 and S2 Systolic vs. Diastolic Murmur characterization	N/A
ECG Rhythm Classification	Sinus Rhythm Atrial Fibrillation Unspecified Rhythm Poor ECG Signal	N/A	Normal Sinus Rhythm Atrial Fibrillation Unclassified ECG Poor ECG Signal
Heart Rate Calculation	Yes, ECG-based or PCG-based	N/A	Yes, ECG-based or PCG-based

PERFORMANCE DATA - NONCLINICAL TESTING SUMMARY

The performance characteristics for the Eko Foundation Analysis Software with Transformers (EFAST) have been evaluated with the following non-clinical testing: software unit, integration, and system-level verification testing consistent with the IEC 62304 standard, and cybersecurity testing.

PERFORMANCE DATA - ALGORITHM PERFORMANCE SUMMARY

Additionally, the EFAST algorithm was validated on proprietary datasets captured with the Eko CORE and CORE 500 Digital Stethoscope. The Eko CORE and CORE 500 Digital Stethoscope were used to capture 15-second duration heart sound and ECG recordings from volunteer patients.

- Structural Murmur Classification

A retrospective study of de-identified data was conducted with the EFAST algorithms to evaluate the structural murmur classification performance. Three sites within the US (n = 2) and Canada (n = 1) contributed data for 2,460 unique heart sound recordings from 615 unique subjects. All heart sound recordings were collected using the Eko CORE (52.7%) or Eko CORE 500 (47.3%) Digital Stethoscopes. 175 (28.5%) patients were pediatric (under 18 years old), and 440 (71.5%) were adults. 355 (57.7%) patients were male, and 260 (42.3%) were female. Race was documented for 458 (74.5%) patients and of that subset, the majority was White (412 [90.0%]), followed by Black or African American (22 [4.8%]), Other (15 [3.3%]), Asian (6 [1.3%]), Native Hawaiian or Other Pacific Islander (2 [$<1\%$]), and American Indian or Alaska Native (1 [$<1\%$]) and therefore representative of the intended use population.

All recordings were annotated by multiple cardiologists in respect to their quality and the presence of any murmur. Ground truth for structural murmur classification was obtained by pairing the cardiologist annotations with gold standard echocardiogram. For 259 of the 2,460 heart sound recordings, the cardiologists could not come to agreement, so the recordings were excluded from analysis.

Of the recordings that the expert cardiologists identified as good signal, 49.5% had a confirmed structural murmur and 50.5% had no structural murmur. Additionally, 96 heart sound recordings were annotated by expert cardiologists to obtain the timing of the S1 and S2 sounds. Cardiologists were blinded to all subject demographic data and echocardiogram findings during annotation.

The following tables demonstrate the results of the primary performance analyses (Structural Murmur Classification and Heart Sound Timing).

	Sensitivity (%)	Specificity (%)
	EFAST	EFAST
Structural Murmur Classification	83.4 (95% CI: 80.2 - 86.6)	86.0 (95% CI: 82.2 - 89.8)

Table 2: EFAST Structural Murmur Classification Performance

Age Group (Years)	EFAST Structural Murmur Classification	
	Sensitivity (%)	Specificity (%)
Pediatric (<18)	85.9 (95% CI: 81.3 - 90.5)	76.0 (95% CI: 68.7 - 83.4)
All Adults (18+)	81.7 (95% CI: 77.5 - 86.0)	93.9 (95% CI: 90.6 - 97.1)
Adults 60+	82.2 (95% CI: 77.7 - 86.8)	90.9 (95% CI: 86.1 - 95.7)

Table 3: EFAST Sensitivity and Specificity at detecting Structural Murmurs at different Age Groups

Heart Sound Timing	Sensitivity (%)	PPV (%)
	EFAST	EFAST
S1 Detection	98.58 (95% CI: 97.21-99.38)	93.27 (95% CI: 90.94-95.15)
S2 Detection	94.81 (95% CI: 92.59-96.53)	94.29 (95% CI: 91.99-96.09)

Table 4: EFAST Heart Sound Timing Performance

The table below shows the observed and adjusted Positive Predictive Values (PPVs) for “High Likelihood” (HL) and “Moderate Likelihood” (ML) predictions for structural murmur. The table shows the probability for Structural Heart Disease given “High Likelihood” and “Moderate

Likelihood” predictions for “Structural Murmur” at different age brackets. For the adjusted PPV calculations at the bottom, the assumption of prevalence is 0.25 (p(SHD)=0.25).

		EFAST Structural Murmur Likelihood	
		PPV _{HL}	PPV _{ML}
Observed	All Ages	90.5 (95% CI: 86.7 - 94.3)	64.7 (95% CI: 55.8 - 73.7)
	Age <18	83.8% (95% CI: 76.7 - 91.0)	45.3% (95% CI: 31.3 - 59.3)
	Age 18+	96.3% (95% CI: 93.1 - 99.5)	81.3% (95% CI: 71.9 - 90.7)
	Age 60+	95.9% (95% CI: 92.3 - 99.4)	80.9% (95% CI: 70.9 - 90.9)
Adjusted for P(SHD) = 0.25	All Ages	76.0 (95% CI: 71.8 - 80.2)	37.9 (95% CI: 35.5 - 40.3)
	Age <18	65.4 (95% CI: 58.4 - 72.4)	23.2 (95% CI: 19.6 - 26.8)
	Age 18+	88.9 (95% CI: 83.7 - 94.1)	57.5 (95% CI: 54.3 - 60.7)
	Age 60+	83.9 (95% CI: 78.4 - 89.5)	48.8 (95% CI: 45.4 - 52.2)

Table 5: Positive Predictive Values (PPVs) for “High Likelihood” (HL) and “Moderate Likelihood” (ML) predictions for structural murmur

Algorithm Performance Comparison to Predicate:

A comparative analysis of the Structural Murmur classification algorithm relative to the predicate device (EMAS - K213794) is shown in the Table below.

	Sensitivity (%)	Specificity (%)
EMAS (K213794)	85.8 (95% CI: 82.9 - 88.7)	84.5 (95% CI: 81.0 - 88.0)
EFAST	83.4 (95% CI: 80.2 - 86.6)	86.0 (95% CI: 82.2 - 89.8)

Table 6: Comparison of sensitivity and specificity between EFAST and EMAS at detecting Structural Murmurs, as measured on the Eko Heart Sound Test Dataset

- ECG Rhythm Classification

A retrospective study of de-identified data was conducted with the EFAST algorithms to evaluate the ECG Rhythm Classification performance. Two sites within the US contributed data for 1,256 ECG recordings from 314 unique subjects. All ECG recordings were collected using the Eko CORE 500 Digital Stethoscope. The median age in the sample was 67.5 (IQR 58-75). 198

(63.1%) patients were male, and 116 (36.9%) were female. The majority of patients were White (272 [86.6%]), followed by Black or African American (19 [6.1%]), Other (15 [2.4%]), Asian (3 [1.0%]), Native Hawaiian or Other Pacific Islander (2 [$<1\%$]), and American Indian or Alaska Native (1 [$<1\%$]) and therefore representative of the intended use population. Race information was unavailable for 2 patients.

All ECG recordings were annotated by multiple experts (*e.g.*, electrophysiologists, certified cardiographic technicians) in respect to their quality and the presence of atrial fibrillation. For 97 of the 1,256 ECG recordings, the experts did not come to an agreement, so the recordings were excluded from analysis.

Of the recordings that the experts identified as good signal, 23.5% had confirmed atrial fibrillation and 76.5% did not have atrial fibrillation (either sinus rhythm or an unspecified rhythm).

The following table demonstrates the results of the primary performance analysis for ECG Rhythm Classification.

	Overall Sensitivity (%)	Overall Specificity (%)
	EFAST	EFAST
Atrial Fibrillation Detection	94.7 (95% CI: 91.5 - 97.8)	94.1 (95% CI: 92.1 - 96.1)

Table 7: EFAST Atrial Fibrillation Detection Performance

Algorithm Performance Comparison to Predicate:

A comparative analysis of the ECG Rhythm classification algorithm relative to the predicate device (EAS - K192004) is shown in the Table below.

	Overall Sensitivity (%)	Overall Specificity (%)
EAS (K192004)	73.1 (95% CI: 66.2 - 80.0)	97.7 (95% CI: 96.5 - 98.9)
EFAST	94.7 (95% CI: 91.5 - 97.8)	94.1 (95% CI: 92.1 - 96.1)

Table 8: Comparison of Overall Sensitivity and Specificity between EFAST and EAS at detecting Atrial Fibrillation, as measured on the Eko ECG Test Dataset

- Heart Rate Calculation

The mean absolute percentage error of the heart-rate algorithm was found to be less than 5%.

Associated Subgroup Analyses

Subgroup assessments of diagnostic performance were conducted to determine if there was heterogeneity in device performance across patient demographics. The results are summarized in Table 9 below.

Subgroup	Results of Test Heterogeneity
Age	For structural murmur classification, age was stratified into three groups: Pediatrics (<18), Adults (18+), Adults (60+). While no significant differences in sensitivity were observed among the age groups, the specificity of tests for pediatric patients (76.0% [95%CI: 68.7-83.4]) showed a lower value compared to those performed on adults (18+) (93.9% [95%CI: 90.6-97.2]). This is likely due to confusion of structural murmurs with some innocent murmurs on pediatric patients. Atrial Fibrillation detection is intended for adults only.
Biological sex	No significant differences were observed across biological sex for both structural murmur classification and Atrial Fibrillation detection.
Race/ethnicity	No significant differences were observed for both structural murmur classification and Atrial Fibrillation detection.

Table 9: Clinical Performance in Pre-Specified Subgroup Analyses

CONCLUSIONS

The indications for use, technological characteristics, and performance testing support that the proposed device, the Eko Foundation Analysis Software with Transformers (EFAST), is substantially equivalent, as safe and effective as the predicate device, and raises no new safety or effectiveness issues.