June 29, 2022

Eko Devices, Inc.
Sam Huang
Director of Regulatory Affairs
1212 Broadway, Suite 100
Oakland, California 94612

Re: K213794
Trade/Device Name: Eko Murmur Analysis Software (EMAS)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC, DPS
Dated: May 28, 2022
Received: June 2, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213794

Device Name
Eko Murmur Analysis Software (EMAS)

Indications for Use *(Describe)*

The Eko Murmur Analysis Software (EMAS) 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 heart murmurs, and the absence of a heart murmur.

The Eko Murmur Analysis Software is not intended as a sole means of diagnosis and is for use in environments where health care 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.

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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GENERAL INFORMATION

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Contact Person:
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Date Prepared: Dec 03, 2021

DEVICE INFORMATION

Trade/Proprietary Name: Eko Murmur Analysis Software (EMAS)
Regulation number: 21 CFR 870.1875
Classification Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC, DPS

PREDICATE DEVICES

CSD Labs GmbH, eMurmur ID (K181988)
Eko Devices, Inc., Eko Analysis Software (K192004)

DEVICE DESCRIPTION

Eko Murmur Analysis Software (EMAS) is a cloud-based service that allows users to upload heart sound/phonocardiogram (PCG) and optional electrocardiogram (ECG) data via an application programming interface (API) for analysis. The software uses signal processing (such as waveform filtering), as well as algorithms derived from machine learning, to analyze the acquired data and generate clinical decision support output for clinicians.
EMAS is designed to evaluate data derived by the company's two previously cleared devices, the Eko DUO (K170874) and Eko CORE (K151319, K200776). The heart sound data from those devices can be transmitted to the Eko Cloud using either the Eko mobile application or third-party applications that use a software development kit (SDK). The EMAS algorithm analyzes the heart sound data and outputs a JSON file with the algorithm results, which is passed down to the requesting application and displayed by the requesting application to the user in the human-readable format.

The analysis will assess the signal quality of the phonocardiogram; detect heart murmurs and classify them as innocent or structural; determine the timing of S1 and S2 heart sounds; and distinguish between systolic and diastolic heart murmurs. As an integral part of a physical assessment, clinicians' interpretations of EMAS' output can help them rule in or out different pathological conditions in a patient.

The EMAS consists of the following algorithm components:

- **Signal Quality Detection Algorithm**:
  This pre-processing algorithm accepts as input the PCG sound from the API controller (*e.g.,* a mobile smartphone application). The algorithm is used to classify PCG recordings based on their signal quality as good or poor.
- **Heart Sound Timing Algorithm**:
  This algorithm detects the presence and timing of specific heart sounds including S1, S2, the systole region, and the diastole region.
- **Murmur Detection & Classification Algorithm**:
  This algorithm is used to identify and classify heart sounds as having "No Murmur", an "Innocent Murmur" (i.e., not pathologic), or a "Structural Murmur" (i.e., pathologic).
- **Murmur Timing Algorithm**:
  This algorithm is used to identify in which regions of the heart cycle (systole vs diastole) a heart murmur occurs if either an "Innocent Murmur" or "Structural Murmur" is identified by the Murmur Detection and Classification Algorithm.

INDICATIONS FOR USE

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 heart murmurs, and the absence of a heart murmur.

The Eko Murmur Analysis Software is not intended as a sole means of diagnosis and is for use in environments where health care 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.

SUBSTANTIAL EQUIVALENCE

Eko Murmur Analysis Software (EMAS) has the same intended use as the predicate devices for providing support to the physician in the evaluation of heart-related physiological data. Additionally, EMAS combines the indications of the predicate devices into a single product: algorithms to classify suspected murmurs as either innocent or structural, similar to that of the eMurmur ID; and algorithms that analyze heart sound data to identify the presence of suspected murmurs, similar to that of the Eko Analysis Software. Any differences in the Eko Murmur

Analysis Software's indication statement, i.e., omission of certain outputs and compatible device information, do not alter the intended diagnostic effect of the device.

Eko Murmur Analysis Software also has similar technological characteristics as the predicate devices in regard to it being a software-only analysis tool that analyzes and classifies heart sound data. EMAS's new technological characteristics, i.e., proprietary analysis algorithms, could affect its safety or effectiveness, but do not raise any different questions of safety or effectiveness, because they analyze the same data (input) to determine the same parameters (output) as those of the predicate devices. The performance testing data shown in this application demonstrate that the Eko Murmur Analysis Software is as safe and as effective as the predicate device(s).

A table comparing the key features of the subject and predicate devices is provided below.

Table 1 Substantial Equivalence Summary Comparison

Parameters	Eko Murmur Analysis Software	eMurmur ID (Primary Predicate)	Eko Analysis Software (Secondary Predicate)
FDA Number	K213794	K181988	K192004
Indications for Use	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 heart murmurs, and the absence of a heart murmur. The Eko Murmur Analysis Software is not intended as a sole means of diagnosis and is for use in	The eMurmur ID software system is a decision support device for the healthcare provider (the user) in the evaluation of patient heart sounds. eMurmur ID is used to record, display, analyze, and store the acoustic signal of the heart, recorded by means of an electronic stethoscope. The automated analysis will identify specific heart sounds that may be present, including S1, S2, physiological heart murmurs, pathological heart murmurs and absence of a heart murmur. eMurmur ID is indicated for use in a setting where auscultation would	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 addition, it calculates certain cardiac time intervals such as heart rate, QRS duration and EMAT. The software does not distinguish

Parameters	Eko Murmur Analysis Software	eMurmur ID (Primary Predicate)	Eko Analysis Software (Secondary Predicate)
	environments where health care 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.	typically be performed by a healthcare provider. It is not intended as a sole means of diagnosis. The heart sound interpretations offered by eMurmur ID are only significant when considered in conjunction with healthcare provider over-read and including all other relevant patient data.	between different kinds of murmurs and does not identify other arrhythmias. 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).
Patient Population	Adult and pediatric patients	Adult and pediatric patients	Adult patients
Device Classification	DQD, DQC, DPS	DQD, DQC	MWI, DQD, DPS
Prescribed	Prescription Only	Prescription Only	Prescription Only
Components	Software Only	Software Only	Software Only
Interface	Callable application programming interface (API)	N/A (Self-contained software application)	Callable application programming interface (API)
Display	No primary display	No primary display	No primary display
Murmur Detection	Yes	Yes	Yes
Murmur Classification	Yes	Yes	No

PERFORMANCE DATA - NONCLINICAL TESTING SUMMARY

The Eko Murmur Analysis Software was the subject of software verification and validation testing, consistent with the principles outlined in FDA's *General Principles of Software Validation; Final Guidance for Industry and FDA Staff* issued May 11, 2005.

PERFORMANCE DATA - CLINICAL TESTING SUMMARY

The algorithms in this submission have been validated using retrospective analysis on a proprietary database. The database contains 2,380 unique heart sound recordings from 615 unique subjects. In the proprietary database, all heart sound recordings were collected using the Eko CORE (67.6%) or Eko DUO (32.4%) digital stethoscopes. The subject population was 42.6% female and had an age range of 0 to 95 years old, race was recorded in 45% of the subjects and out of that subset, 98% were white, 1.5% were African American and 0.7% were Asian. No complications or adverse events were experienced during the use of the EMAS device.

All recordings were annotated by multiple cardiologists in respect to their quality and the presence of any murmur. Of the recordings identified as being good signal by the expert cardiologists, 45.8% had a confirmed structural murmur and 54.2% had a confirmed no murmur or innocent murmur. Ground truth for murmur classification was obtained via pairing cardiologist annotations with gold standard echocardiogram. Additionally, 299 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.

No study subjects included in the training datasets were included in the test database. All algorithm testing was performed once the final EMAS version was locked.

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

Table 2 EMAS Murmur Classification Performance

	Sensitivity (%)	**Specificity (%)**
Murmur Classification	85.6 (95% CI: 82.6 - 88.7)	84.4 (95% CI: 81.3 - 87.5)

The lower bounds of the 95% confidence intervals of the primary predicate device are 72.9% and 74.9% for sensitivity and specificity, respectively. Through clinical validation, the lower bound of EMAS' calculated 95% confidence interval is found to be above 75.0%, thus demonstrating substantially equivalent performance (effectiveness) to the predicate device (eMurmur).

Table 3 EMAS Heart Sound Timing Performance

		Sensitivity (%)	PPV (%)
Heart Sound Timing	**S1 Detection**	96.2 (95% CI: 94.9 - 97.4)	97.1 (95% CI: 96.3 - 98.0)
	S2 Detection	92.3 (95% CI: 90.3 - 94.3)	94.3 (95% CI: 93.4 - 95.1)

Given the data described above, the EMAS algorithm testing shows substantially equivalent performance to the predicate devices where applicable. Based on the clinical performance, the Eko Murmur Analysis Software has a safety and effectiveness profile that is similar to the predicate devices.

CONCLUSIONS

The Eko Murmur Analysis Software is as safe and as effective as the predicate devices. The Eko Murmur Analysis Software has the same intended uses and similar indications, technological characteristics, and principles of operation as its primary predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not raise different questions of safety and effectiveness when used as labeled. In addition, the minor technological differences between the Eko Murmur Analysis Software and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Eko Murmur Analysis Software is as safe and effective as the predicate devices. Thus, the Eko Murmur Analysis Software is substantially equivalent.