January 15, 2020

Eko Devices Inc
% Yarmela Pavlovic
Partner
Manatt, Phelps & Phillips, LLP
One Embarcadero Center, 30th Floor
San Francisco, California 94111

Re: K192004
Trade/Device Name: Eko Analysis Software
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQD, DPS
Dated: December 18, 2019
Received: December 18, 2019

Dear Yarmela Pavlovic:

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,

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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K192004

Device Name

Eko Analysis Software (EAS)

Indications for Use *(Describe)*

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 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).

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

Eko Devices, Inc.'s Eko Analysis Software

Submitter

Eko Devices Inc,
2600 10th Street, Suite #260,
Berkeley, CA - 94710

Contact Person: Subramaniam Venkatraman, CTO
Phone: 844-356-3384
Email: contact@ekohealth.com

Date Prepared: January 8, 2020

Name of Device: Eko Analysis Software (EAS)
Common or Usual Name: CardiacAI

Classification Name: Cardiac monitor
Regulatory Class: Class II
Product Code: MWI, DQD, DPS

Predicate Devices

Dictum Health Inc., IDM100 (K170798)
Diacoustic Medical Devices (Pty) Ltd, SensiCardiac Mobi (K131044)
Inovise Medical, AUDICOR 200 (K073545)
physIQ Inc, physIQ Heart Rhythm Module (K180234)

Device Description

The Eko Analysis Software is a cloud-based software API that allows a user to upload synchronized ECG and heart sound/phonocardiogram (PCG) data for analysis. The software uses several methods to interpret the acquired signals including signal processing and artificial neural networks. The API can be electronically interfaced, and perform analysis with data transferred from multiple mobile or computer based applications.

The EAS software is only intended to be used in conjunction with data acquired using two previously-cleared physiological data acquisition devices (Eko DUO (K170874) and Eko CORE (K151319)). The software is designed to be used with companion mobile apps that are used during data acquisition. After analysis, results are returned through an interface to the mobile apps for display.

The algorithm consists of the following components:

- Rhythm detection algorithm: A neural network model that uses ECG to detect normal sinus rhythm and atrial fibrillation.
- Murmur detection algorithm: A neural network model that uses heart sounds to detect the presence of murmurs.
- Heart rate analysis algorithm: A signal processing algorithm that uses ECG or heart sounds as appropriate to calculate heart rate. It also provides an alert if the measured heart rate is indicative of Bradycardia or Tachycardia.

- QRS duration algorithm: A signal processing algorithm that measures the width of the QRS pulse on a single-channel ECG.
- EMAT Interval algorithm: A signal processing algorithm that uses Q peak detection and S1 envelope detection to measure the Q-S1 interval, defined as electromechanical activation time or EMAT.

Intended Use / Indications for Use

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 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).

Summary of Technological Characteristics

EAS combines the features of multiple predicate devices into a single combined software package. The intended use of the subject product (i.e., analysis of physiological data) is the same as that of all of the predicate devices and the indications for use and technological characteristics are either identical or very similar between the subject device and each relevant predicate. Any differences in specific analyzed parameters (indications for use) do not raise different questions of safety or effectiveness in comparison to the predicates. While some of the predicate devices feature additional technological capabilities (e.g., the SensiCardiac predicate additional features differentiation between pathologic and innocent murmur, while the subject device and predicate both differentiate between the presence of murmur and no murmur), this does not raise different questions of safety or effectiveness because in all cases the subject device features are a subset of those cleared for the predicates.

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

	Eko Analysis Software	IDM100	Sensi Cardiac Mobi Diagnostic Heart Murmur Application	AUDICOR 200	physIQ Heart Rhythm Module (version 1.0)
510K Number	K182119	K170798	K131044	K073545	K180234
Patient Population	Adult patients	Neonate (up to 28 days); pediatric (29 days to 12 years, excepted as noted); adolescent (13-17 years); adult (18 years and older)	Adult and pediatric patients	Patients over 18 years of age	Adult patients
Intended User	Physicians	Physicians and patients	Physicians	Physician	Physician or other qualified medical professionals
Standards Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 IED 60601-2-25 ANSI/AAMI EC57	ANSI/AAMI EC53 EN/IEC 60601-2-25 EN/IEC 60601-2-51	IEC 60601-1 IEC 60601-1-2	EN 60601-1 EN60601-1-2 IEC 60601-2-25 IEC 60601-2-51	ANSI/AAMI EC57
Device Classification	MWI, DQD, DPS	MWI	DQD, DQC	DPS, DQD, MLO	DPS
Prescribed	Prescription Only	Prescription Only	Prescription Only	Prescription Only	Prescription Only
Components	Software Only	Software + Hardware	Software Only	Software + Hardware	Software Only
Interface	Application programming interface (API)				Callable application programming interface (API)
Display	No primary display	Yes	No primary display	Yes on Audicor-enabled laptop	No primary display
Physiological Inputs	Heart sounds and ECG data	Heart sounds, ECG data, SpO2, NIBP	Heart sounds	Heart sounds and ECG data	Heart sounds and ECG data
Murmur Detection	Yes (classification)	No	Yes (classification)	No	No
A-fib detection	Yes (classification)	No, ECG acquisition only.	No	No	Yes (classification)
EMAT Calculation	Yes	No	No	Yes	No
Heart Rate Calculation	Yes	Yes	Yes	Yes	Yes
QRS duration Calculation	Yes	No	No	Yes	Yes

Performance Data – Nonclinical Testing

The Eko 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*.

Performance Data – Clinical Testing

The algorithms in this submission have been validated using retrospective analysis on a combination of publicly available (MIT-BIH Arrhythmia Database, MIT-BIH Arrhythmia Noise Stress Database, AHA Database, NST Database, Physionet QT Database, and PhysioNet 2016 Database) and proprietary datasets captured with the Eko CORE and Eko DUO. In the proprietary datasets, the Eko CORE and Eko DUO were used to capture 15 second long heart sound and ECG recordings from chests of individual volunteers. A total of 732 recording were captured from 139 patients using the Eko DUO and 1445 recordings were captured from 236 patients using the Eko CORE. In the Eko DUO dataset 54.7% of patients were female and all patients were over the age of 18, with the largest percentage being 61 to 80 years of age. Additionally, 79.9% were white, while 9.4% were Asian and the remainder were Black or African American, American Indian or Alaskan Native, Native Hawaiian or Pacific Islander or Hispanic/Latino. In the Eko CORE dataset, 47.9% of patients were female. Additionally, 83.9% were white, 7.6% were black or African American and the remainder were Asian (4.2%), Hispanic or Latino (2.1%) or other/unknown. Patients were all over the age of 18 with the largest percentage being 51 to 80 years of age.

A brief description of the testing provided for each individual analysis algorithm is provided below along with performance results from the most relevant datasets:

Rhythm Detection

Testing was carried out on publicly available databases as well as the EKO ECG dataset. When the device was tested with the EKO ECG dataset, 74.3% (544/732) of ECG recordings were classified as either Normal or Atrial Fibrillation. Sensitivity and specificity measured in the classifiable ECGs were 100% (95% CI: 93.8 – 100.0) and 96.2% (95% CI: 93.8 - 97.7), respectively.

Murmur Detection

Testing was carried out on the Eko Heart Sound Database comprised of data collected using both the Eko CORE and Eko DUO devices. Sensitivity and specificity in the Eko Heart Sound Database were 87.6% (95% CI: 84.2 – 90.5) and 87.8% (95% CI: 85.3 – 89.9), respectively.

Heart Rate Calculation

Testing was carried out on publicly available datasets as well as the EKO ECG dataset (described above). Bradycardia and Tachycardia detection accuracy was also measured in the publicly available datasets. Heart rate error measured in the MIT-BIH dataset was 1.14% (95% CI: 0.95 – 1.34). Bradycardia detection had a sensitivity and specificity of 94.7% (95%

CI: 89.8 – 97.3) and 99.7% (95% CI: 99.4 – 99.8) respectively. Tachycardia detection had a sensitivity and specificity of 93.6% (95% CI: 90.9 – 95.6) and 99.0% (95% CI: 98.7 – 99.3) respectively.

QRS Duration Calculation

Testing was carried out using the publicly available PhysioNet QT database. Absolute Mean Error (ms) for calculating QRS duration was 9.25 (95% CI: 7.93 – 10.58).

EMAT Calculation

Testing was carried out on publicly available Physionet 2016 database, as well as the Eko ECG dataset. Absolute Error in the Physionet 2016 dataset was 1.68% (95% CI: 1.06 - 2.30).

Given the data described above, the algorithms performed as expected. Based on the clinical performance the Eko Analysis Software has a safety and effectiveness profile that is similar to the predicate devices.

Conclusions

The Eko Analysis Software is as safe and effective as the predicate devices. The Eko Analysis Software has the same intended uses and similar indications, technological characteristics, and principles of operation as its 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 Analysis Software and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Eko Analysis Software is as safe and effective as the predicate devices. Thus, the Eko Analysis Software is substantially equivalent.