May 26, 2023

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

Re: K230111
Trade/Device Name: CORE 500 Digital Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: January 13, 2023
Received: January 17, 2023

Dear Sam Huang, Ph.D.:

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,

Robert T. Kazmierski -S

for

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)*
K230111

Device Name
CORE 500 Digital Stethoscope

Indications for Use *(Describe)*
The CORE 500 Digital Stethoscope is intended to be used by clinicians to electronically amplify, filter, and transfer body sounds and three lead electrocardiogram (ECG) waveforms. The CORE 500 Digital Stethoscope also displays ECG waveforms and heart rate on the display and accompanying mobile application (when prescribed or used under the care of a clinician).

The data offered by the device is only significant when used in conjunction with clinician evaluation as well as consideration of other relevant patient data.

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

Applicant:
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Phone: 844-356-3384

Contact Person:
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Director of Regulatory Affairs
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Date Prepared: January 13, 2023

DEVICE INFORMATION

Trade/Proprietary Name: CORE 500 Digital Stethoscope
Regulation number: 21 CFR 870.1875
Device Classification Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD, DPS

PREDICATE DEVICE

Predicate Device: Eko Model E5 System (EME5), Eko DUO (K170874)
Reference Device: Eko Analysis Software (EAS) (K192004)

DEVICE DESCRIPTION

CORE 500 Digital Stethoscope (CORE 500) is an electronic stethoscope with integrated electrodes for electrocardiogram (ECG). The device consists of a chestpiece, detachable earpiece (Eko Earpiece) and a mobile application (Eko App) and is intended as a digital auscultation tool on patients requiring physical assessment by the health care providers. CORE 500 provides the ability to amplify, filter, and transfer body sounds with the chestpiece diaphragm, and three lead ECG through electrodes integrated around the chestpiece.

CORE 500 features three auscultation modes for better auscultation experience by filtering acoustic data and enhancing the primary frequency range of particular body sounds: Cardiac Mode for heart sounds, Pulmonary Mode for lung sounds, and Wide Band Mode for general auscultation. CORE 500 also detects and computes the heart rate in real-time based on the phonocardiogram (PCG) data.

INDICATIONS FOR USE

The CORE 500 Digital Stethoscope is intended to be used by clinicians to electronically amplify, filter, and transfer body sounds and three lead electrocardiogram (ECG) waveforms. The CORE 500 Digital Stethoscope also displays ECG waveforms and heart rate on the display and accompanying mobile application (when prescribed or used under the care of a clinician).

The data offered by the device is only significant when used in conjunction with clinician evaluation as well as consideration of other relevant patient data.

SUBSTANTIAL EQUIVALENCE

The CORE 500 Digital Stethoscope (CORE 500) is substantially equivalent to its predicate devices with regard to the intended use and the indications for use. Any differences in technological characteristics do not raise new questions on safety or effectiveness compared to the predicate device. A substantial equivalence comparison table between the subject device and the predicate device is provided below.

Table 1 Substantial Equivalence Summary Comparison

	Subject Device: CORE 500 Digital Stethoscope	**Predicate Device: Eko Model E5 System (EME5), Eko DUO (K170874)**	**Reference Device: Eko Analysis Software (EAS) (K192004)**	**Comparison**
Device Classification Name	Electronic Stethoscope	Electronic Stethoscope	Cardiac Monitor	Same as the predicate
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	21 CFR 870.2300	Same as the predicate
Classification Product Code	DQD, DPS	DQD, DPS	MWI, DQD, DPS	Same as the predicate
Indications for Use	The CORE 500 Digital Stethoscope is intended to be used by clinicians to electronically amplify, filter, and transfer body sounds and three lead electrocardiogram (ECG) waveforms. The CORE 500 Digital Stethoscope also displays ECG waveforms and heart rate on the display and accompanying mobile application (when prescribed or used under the care of a clinician). The data offered by the	The Eko Model E5 System is intended to be used by healthcare professionals to electronically amplify, filter, and transfer body sounds and single-channel electrocardiogram (ECG) waveforms. The Eko Model E5 System also displays ECG waveforms and phonocardiogram waveforms on the accompanying mobile application for storage and sharing (when prescribed or used under the care of a physician). It can be used to record heart sounds and cardiac	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	Same intended use and indications for use as the predicate

	Subject Device: CORE 500 Digital Stethoscope	Predicate Device: Eko Model E5 System (EME5), Eko DUO (K170874)	Reference Device: Eko Analysis Software (EAS) (K192004)	Comparison
	device is only significant when used in conjunction with clinician evaluation as well as consideration of other relevant patient data.	murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems. The device can be used on adults and pediatrics. The data offered by the device is only significant when used in conjunction with physician over read as well as consideration of other relevant patient data. The device should not be used on infants weighing less than 10kg.	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).	
Patient Population	Adults and pediatric patients	Adults and pediatric patients	Adults (> 18 years)	Same as the predicate
Prescribed	Prescription Only	Prescription Only	Prescription Only	Same as the predicate
Technological Characteristics Comparison				

	Subject Device: CORE 500 Digital Stethoscope	**Predicate Device: Eko Model E5 System (EME5), Eko DUO (K170874)**	**Reference Device: Eko Analysis Software (EAS) (K192004)**	**Comparison**
Type of Data Acquired	Body sounds and ECG	Body sounds and ECG	N/A as EAS is a standalone software	Same as the predicate
Connectivity	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	N/A as EAS is a standalone software	Same as the predicate
Battery Type	Rechargeable Lithium-ion, 3.7V	Rechargeable lithium-ion, 3.7V	N/A as EAS is a standalone software	Same as the predicate
Audio Frequency Range	20 Hz - 2000 Hz	20 Hz - 2000 Hz	N/A as EAS is a standalone software	Same as the predicate
ECG Frequency Range	0.1 - 250 Hz	0.15 - 200 Hz	N/A as EAS is a standalone software	Similar to the predicate. The subject device has wider frequency range that does not raise different questions of safety and effectiveness
Mechanism of Action	User places the device on the body for auscultation. The device simultaneously captures ECG, and Audio data which is transmitted via	User places the device on the body for auscultation. The device simultaneously captures ECG, and Audio data which is transmitted via Bluetooth to the	N/A as EAS is a standalone software	Same as the predicate

	Subject Device: CORE 500 Digital Stethoscope	**Predicate Device: Eko Model E5 System (EME5), Eko DUO (K170874)**	**Reference Device: Eko Analysis Software (EAS) (K192004)**	**Comparison**
	Bluetooth to the Mobile application.	Mobile application.		
No. of ECG Electrodes	Three (3) dry electrodes	Two (2) dry electrodes	N/A as EAS is a standalone software	Different. The technology characteristic difference does not raise different questions of safety and effectiveness
Hardware Interface	Display Mode Button Volume Button Capacitive touch	Mode Button Volume Button	N/A as EAS is a standalone software	Similar to the predicate. The additional interfaces do not raise different questions of safety and effectiveness
Software Interface	Mobile Application (Eko App)	Mobile Application (Eko App)	N/A as EAS is a standalone software	Same as the predicate
Recording and Playback	Yes	Yes	N/A as EAS is a standalone software	Same as the predicate
Heart Rate Detection	PCG-based	N/A	ECG-based and/or PCG-based	Similar to the reference

	Subject Device: CORE 500 Digital Stethoscope	**Predicate Device: Eko Model E5 System (EME5), Eko DUO (K170874)**	**Reference Device: Eko Analysis Software (EAS) (K192004)**	**Comparison**
				device
Visualization of Sound and ECG Waveforms	Yes	Yes	N/A as EAS is a standalone software	Same as the predicate
Auscultation Mode	Cardiac Mode Pulmonary Mode Wide Band Mode	Diaphragm Mode Pulmonary Mode Bell Mode	N/A as EAS is a standalone software	Similar to the predicate. The filter setting difference does not raise different questions of safety and effectiveness

PERFORMANCE DATA - NONCLINICAL TESTING SUMMARY

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility
Biological evaluations were conducted with the CORE 500 Digital Stethoscope according to ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The evaluation report concluded that the CORE 500 Digital Stethoscope is biocompatible.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted and demonstrated CORE 500 Digital Stethoscope complies with IEC 60601-1, IEC 60601-1-11, IEC 60601-2-47 standard for safety, IEC 60601-1-2 for electromagnetic compatibility.

Software verification and validation testing
The software of this device is verified and validated according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Bench testing
The CORE 500 Digital Stethoscope has gone through rigorous bench testing to demonstrate the product performance, and confirmed that differences between the subject and predicate device do not raise different questions of safety and effectiveness. The testing includes the following:

- Audio performance
- Electrical and mechanical function verification, and
- Heart rate measurement

CONCLUSIONS

The indications for use, technological characteristics and performance testing support that the proposed device, the CORE 500 Digital Stethoscope is substantially equivalent, and as safe and effective as the predicate device, and raises no new issues of safety or effectiveness.