March 28, 2024

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

Re: K233609
Trade/Device Name: CORE 500 Digital Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DPS
Dated: November 8, 2023
Received: November 8, 2023

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.

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,
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233609

Device Name

CORE 500 Digital Stethoscope

Indications for Use *(Describe)*

The CORE 500 Digital Stethoscope is intended to be used by clinicians or lay users 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 or by lay users).

A lay user is not intended to interpret or take clinical action based on the device output without consulting with a qualified healthcare professional.

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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Director of Regulatory Affairs
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Date Prepared: November 9, 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

Primary Predicate: CORE 500 Digital Stethoscope (K230111)
Reference Device: Eko CORE (K200776)

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 clinicians or lay users. 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. The device can be used in a professional healthcare facility and for home use.

CORE 500 features three auscultation modes for a 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 or lay users 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 or by lay users).

A lay user is not intended to interpret or take clinical action based on the device output without consulting with a qualified healthcare professional.

SUBSTANTIAL EQUIVALENCE

The CORE 500 Digital Stethoscope (CORE 500) has the same intended use, the same technological characteristics as its predicate device. The differences in user groups 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

Feature	Subject Device: CORE 500 Digital Stethoscope	Predicate Device: CORE 500 Digital Stethoscope (K230111)	Reference Device: Eko CORE (K200776)	Comparison
Device Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope	Same
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	21 CFR 870.1875	Same
Classification Product Code	DQD, DPS	DQD, DPS	DQD	Same as the predicate device
Indications for Use	The CORE 500 Digital Stethoscope is intended to be used by clinicians or lay users to electronically amplify, filter, and transfer body sounds	The CORE 500 Digital Stethoscope is intended to be used by clinicians to electronically amplify, filter, and transfer body sounds and three lead	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound	Same intended use as the predicate device, different user groups. The user

Feature	Subject Device: CORE 500 Digital Stethoscope	Predicate Device: CORE 500 Digital Stethoscope (K230111)	Reference Device: Eko CORE (K200776)	Comparison
	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 or by lay users). A lay user is not intended to interpret or take clinical action based on the device output without consulting with a qualified healthcare professional.	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.	data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.	group difference does not raise different questions of safety and effectiveness
Patient Population	Adults and pediatric patients	Adults and pediatric patients	Adults and pediatric patients	Same
Prescribed	Over-the-Counter Use	Prescription Only	Over-the-Counter Use	The proposed OTC use is the same as the reference device
Technological Characteristics Comparison				
Type of Data Acquired	Body sounds and ECG	Body sounds and ECG	Body sounds	Same as the predicate device
Connectivity	Bluetooth Low	Bluetooth Low	Bluetooth	Same as the

Feature	Subject Device: CORE 500 Digital Stethoscope	Predicate Device: CORE 500 Digital Stethoscope (K230111)	Reference Device: Eko CORE (K200776)	Comparison
	Energy (BLE)	Energy (BLE)		predicate device
Battery Type	Rechargeable Lithium-ion, 3.7V	Rechargeable lithium-ion, 3.7V	Rechargeable 3.7 V Lithium-ion polymer cell	Same as the predicate device
Audio Frequency Response Range	Bandwidth of 20 Hz - 2000 Hz	Bandwidth of 20 Hz - 2000 Hz	Bandwidth of 20 Hz - 2000 Hz	Same
ECG Performance (ECG Frequency Response Range)	0.1 - 250 Hz	0.1 - 250 Hz	N/A	Same as the predicate device
Mechanism of Action	User places the device on the body for auscultation. The device simultaneously captures ECG, and Audio data which is transmitted via Bluetooth to the Mobile application.	User places the device on the body for auscultation. The device simultaneously captures ECG, and Audio data which is transmitted via Bluetooth to the Mobile application.	User places the device on the body for auscultation. The device captures Audio data which is transmitted via Bluetooth to the Mobile application.	Same as the predicate device
No. of ECG Electrodes	Three (3) dry electrodes	Three (3) dry electrodes	N/A	Same as the predicate device
Hardware Interface	Display Mode Button Volume Button Capacitive touch	Display Mode Button Volume Button Capacitive touch	Volume Button	Same as the predicate device
Software Interface	Mobile Application (Eko App)	Mobile Application (Eko App)	Mobile Application (Eko App)	Same

Feature	Subject Device: CORE 500 Digital Stethoscope	Predicate Device: CORE 500 Digital Stethoscope (K230111)	Reference Device: Eko CORE (K200776)	Comparison
Recording and Playback	Yes	Yes	Yes	Same
Heart Rate Detection	PCG-based	PCG-based	N/A	Same as the predicate device
Visualization of Sound and ECG Waveforms	Yes	Yes	N/A	Same as the predicate device
Auscultation Mode	Cardiac Mode Pulmonary Mode Wide Band Mode	Cardiac Mode Pulmonary Mode Wide Band Mode	Cardiac Mode Pulmonary Mode Wide Band Mode	Same as the predicate device

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 standards for safety, IEC 60601-1-2 for electromagnetic compatibility.

Software Verification and Validation Testing
The software of the subject device is verified and validated according to the FDA guidance for the Content of Premarket Submissions for Device Software Functions.

Usability Testing
Human factors usability testing was conducted per IEC 62366-1 to evaluate that the intended users of the CORE 500 Digital Stethoscope are able to achieve its intended use with the help of the Instructions for Use.

Nonclinical 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.