July 23, 2026

Eko Health, Inc.
Min Cao
Project Manager, Regulatory Affairs
2100 Powell St.
Suite 300
Emeryville, California 94608

Re: K261694
Trade/Device Name: CORE 300 Digital Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 22, 2026
Received: May 22, 2026

Dear Min Cao:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

CDR 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)*
K261694

Device Name
CORE 300 Digital Stethoscope

Indications for Use *(Describe)*
The CORE 300 Digital Stethoscope is intended to electronically amplify, filter, and transmit body sounds, and to calculate heart rate. The device is intended for use by healthcare professionals or lay users on pediatric and adult patients.

For lay users, the device output is not intended to be interpreted or used to take clinical action without consultation with a 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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GENERAL INFORMATION

Applicant:
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Phone: 844-356-3384

Contact Person:
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Date Prepared: May 20, 2026

DEVICE INFORMATION

Trade/Proprietary Name: CORE 300 Digital Stethoscope
Regulation number: 21 CFR 870.1875
Device Classification Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD

PREDICATE DEVICE

Predicate Device: Eko CORE (K200776)
Reference Device: CORE 500 Digital Stethoscope (K233609)

DEVICE DESCRIPTION

The CORE 300 Digital Stethoscope (CORE 300) is an electronic stethoscope intended to amplify, filter, and transmit body sounds. The device has a form factor consistent with a traditional stethoscope and includes a chestpiece with an integrated display and a semi-permanently attached binaural earpiece. The device operates in two modes: traditional mode, when powered off, and digital mode, when powered on. In traditional mode, the device functions as a traditional stethoscope without requiring battery power. The operating mode is selected via a twist mechanism at the connection between the chestpiece and the binaural; rotating to the ON position activates digital mode, and rotating to the OFF position returns the device to traditional mode.

In digital mode, the CORE 300 Digital Stethoscope provides three audio filter modes for

auscultation that process acoustic data to emphasize frequency ranges associated with specific body sounds: Cardiac Mode for heart sounds, Pulmonary Mode for lung sounds, and All-Purpose Mode for general auscultation. The device also calculates heart rate in real time using phonocardiogram (PCG) data. Heart rate is displayed on the chestpiece display and, when connected, in the associated software applications.

INDICATIONS FOR USE

The CORE 300 Digital Stethoscope is intended to electronically amplify, filter, and transmit body sounds, and to calculate heart rate. The device is intended for use by healthcare professionals or lay users on pediatric and adult patients.

For lay users, the device output is not intended to be interpreted or used to take clinical action without consultation with a healthcare professional.

SUBSTANTIAL EQUIVALENCE

The CORE 300 Digital Stethoscope has the same general intended use and similar technological characteristics as the predicate device, Eko CORE (K200776). Both devices are electronic stethoscopes intended to electronically amplify, filter, and transmit body sounds for use on pediatric and adult patients by healthcare professionals or lay users.

CORE 300 additionally calculates heart rate using phonocardiogram (PCG) data and includes an integrated display for presentation of device-related information, including heart rate, as applicable. These differences do not alter the fundamental intended use or principle of operation of the device as an electronic stethoscope because the heart-rate calculation is derived from the same body sound data acquired during auscultation, and the display represents an additional location for presenting device information. These differences do not introduce a new signal modality. CORE 500 Digital Stethoscope (K233609) is cited as a reference device to support the PCG-based heart-rate calculation methodology, display-related comparison, and related performance considerations.

The differences in technological characteristics between CORE 300 and the predicate device do not raise different questions of safety and effectiveness. Performance testing supports that CORE 300 is substantially equivalent to the predicate device.

A substantial equivalence comparison table between the subject device, predicate device, and reference device is provided below.

Table 1 Substantial Equivalence Summary Comparison

Feature	Subject Device: CORE 300 Digital Stethoscope	Predicate Device: Eko CORE (K200776)	Reference Device: CORE 500 Digital Stethoscope (K233609)	Comparison Conclusion
Device Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope	Same as the predicate device
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	21 CFR 870.1875	Same as the predicate device
Classification Product Code	DQD	DQD	DQD, DPS	Same as the predicate device (The reference device includes an additional DPS product code due to ECG functionality, which is not included in CORE 300)
Indications for Use	The CORE 300 Digital Stethoscope is intended to electronically amplify, filter, and transmit body sounds, and to calculate heart rate. The device is intended for use by healthcare professionals or lay users on pediatric and adult patients. For lay users, the device output is not intended to be interpreted or used	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound 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	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	Same general intended use and user groups as the predicate device

Feature	Subject Device: CORE 300 Digital Stethoscope	Predicate Device: Eko CORE (K200776)	Reference Device: CORE 500 Digital Stethoscope (K233609)	Comparison Conclusion
	to take clinical action without consultation with a healthcare professional.	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.	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.	
Patient Population	Adults and pediatric patients	Adults and pediatric patients	Adults and pediatric patients	Same as the predicate device
Prescription/ OTC Status	Over-the-Counter Use	Over-the-Counter Use	Over-the-Counter Use	Same as the predicate device
Technological Characteristics Comparison				
Type of Data Acquired	Body sounds	Body sounds	Body sounds and ECG	Same as the predicate device
Connectivity	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Same as the predicate device
Battery Type	Rechargeable 3.7 V Lithium-ion polymer cell	Rechargeable 3.7 V Lithium-ion polymer cell	Rechargeable Lithium-ion, 3.7V	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 as the predicate device
Mechanism of Action	User places the device on the body for auscultation. The device captures Audio data which is	User places the device on the body for auscultation. The device captures Audio data which is	User places the device on the body for auscultation. The device simultaneously	Same as the predicate device

Feature	Subject Device: CORE 300 Digital Stethoscope	Predicate Device: Eko CORE (K200776)	Reference Device: CORE 500 Digital Stethoscope (K233609)	Comparison Conclusion
	transmitted via Bluetooth to the Mobile application	transmitted via Bluetooth to the Mobile application.	captures ECG, and Audio data which is transmitted via Bluetooth to the Mobile application.	
Hardware Interface	Display Mode Button Volume Button	Mode Button Volume Button	Display Mode Button Volume Button Capacitive Touch	Similar to the predicate device. CORE 300 includes a display, which is a technological difference from the predicate device and is consistent with the reference device. This difference does not alter the device's fundamental principle of operation or raise different questions of safety and effectiveness
Software Interface	Mobile Application (Eko App)	Mobile Application (Eko App)	Mobile Application (Eko App)	Same as the predicate device
Recording and Playback	Yes	Yes	Yes	Same as the predicate device
Heart Rate Detection	PCG-based	N/A	PCG-based	Additional feature compared to the predicate device; PCG-based

Feature	Subject Device: CORE 300 Digital Stethoscope	Predicate Device: Eko CORE (K200776)	Reference Device: CORE 500 Digital Stethoscope (K233609)	Comparison Conclusion
				heart-rate calculation is consistent with the reference device and supported by performance testing
Audio Filter	Cardiac Mode Pulmonary Mode All-Purpose Mode	Cardiac Mode Pulmonary Mode Wide Band Mode	Cardiac Mode Pulmonary Mode Wide Band Mode	Same audio filter mode categories as the predicate device. CORE 300 uses the user-facing term "All-Purpose Mode" for the Wide Band Mode. This terminology difference does not change the underlying audio filtering functionality or raise different questions of safety and effectiveness.
Operating Mode	Traditional Mode Digital Mode	Traditional Mode Digital Mode	Digital 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
A biological evaluation was conducted for the patient-contacting materials of the CORE 300 Digital Stethoscope in accordance with the applicable FDA-recognized biocompatibility framework and ISO 10993-1. The evaluation concluded that the device is biocompatible for its intended patient-contacting use.

Electrical Safety and Electromagnetic Compatibility
Electrical safety and electromagnetic compatibility testing were conducted to demonstrate that CORE 300 complies with applicable IEC 60601-1, IEC 60601-1-11, and IEC 60601-1-2 requirements.

Software Verification and Validation
Software verification and validation activities were conducted in accordance with FDA's guidance, Content of Premarket Submissions for Device Software Functions. The testing verified that the device software functions perform as intended and support the device's intended use.

Cybersecurity
Cybersecurity documentation and risk management activities were provided in accordance with FDA's current cybersecurity guidance for connected medical devices. The assessment supports that the cybersecurity risks associated with the device and associated mobile application are appropriately controlled for the intended use environment.

Bench Performance Testing
Bench performance testing was conducted to demonstrate that the CORE 300 Digital Stethoscope performs as intended and that differences from the predicate device do not raise different questions of safety and effectiveness. Testing included:

- Audio performance
- Electrical and mechanical functional verification
- Heart rate measurement performance

CONCLUSIONS

Based on the intended use, technological characteristics, risk analysis, and performance testing, the CORE 300 Digital Stethoscope is substantially equivalent to the predicate device, Eko CORE (K200776). The differences between CORE 300 and the predicate device do not raise different questions of safety and effectiveness. The nonclinical performance data support that CORE 300 is as safe and effective as, and performs as well as, the legally marketed predicate device.