April 6, 2020

Eko Devices, Inc.
Arezou Azar
Sr. Dir. Regulatory Affairs
1212 Broadway, Suite 100
Oakland, California 94612

Re: K200776
Trade/Device Name: Eko CORE
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: March 23, 2020
Received: March 25, 2020

Dear Arezou Azar:

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,

LT 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)*
K200776

Device Name
Eko CORE

Indications for Use *(Describe)*
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 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.

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. Eko CORE

Submitter Name and Address: Eko Devices, Inc.
1212 Broadway, Suite 100
Oakland, CA 94612

Contact Person: Arezou Azar, PhD.
Sr.Dir of Regulatory Affairs
Email: arezou.azar@ekohealth.com
Phone: 650-804-0285

Device Trade Name(s): Eko CORE
Other Names Used: Eko Electronic Stethoscope System
CORE by Eko
Common or Usual Name: Electronic Stethoscope
Classification Name: Electronic Stethoscope
Regulatory Class: Class II
Product Code: DQD, 870.1875
Predicate Devices: Eko Electronic Stethoscope System (EESS)(K151319), Eko Devices, Inc.
Tyto Stethoscope (K181612) (OTC), Tyto Care Ltd.

Device Description

The Eko CORE (OTC) is a digital stethoscope device designed for use by health care professionals as well as lay users in clinical or non-clinical environments. It enables physicians transition between traditional and digital auscultation. It can electronically amplify, filter and transfer sounds to the accompanying mobile application for storage and sharing or can transmit the data for telemedicine use. It also enables regular users to listen to their body sounds (lungs, heart, arteries, veins, Gastrointestinal tract, etc.) and record and share it with their physicians.

It consists of two primary components: 1) The CORE: an electronic attachment for an analog stethoscope and 2) Eko App, and application that pairs with the CORE attachment.

- CORE is used to record audio in the stethoscope, convert it to digital data points, and transmit data to a mobile device via Bluetooth®. It includes a volume adjustment button, an analog-to-digital power switch, and an LED light indicator.
- The app captures audio data from the CORE and provides data visualization, secure data storage, audio playback, and sharing features.

These features enable a healthcare professional to monitor patients, seek out second opinions from a specialist or use the device for telemedicine use.

Intended Use / Indications for Use

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 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.

Summary of Technological Characteristics

The Eko CORE is a modified version of the previously-cleared predicate device and has very similar technological characteristics. Minor changes have been made, but the devices have the same overall operational and technological characteristics. Both devices include the ability to attach to a standard analog stethoscope and feature both digital and analog auscultation modes. Additionally, both devices connect via Bluetooth to the Eko App for visualization, recording and transfer of data. Both devices included on/off power buttons and volume adjustment controls. Both devices have the same frequency range and have the same maximum sound level.

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

Performance Data

The device has undergone extensive bench verification, as well as software verification and validation. Electrical safety, EMC and wireless coexistence testing were also successfully conducted.

The OTC use of the device was assessed in human factors testing with passing results.

In all instances, the device functioned as intended. Based on the testing results, the device has a safety and effectiveness profile that is similar to the predicate device.

Conclusions

The Eko CORE is as safe and effective as the predicate devices. The Eko CORE 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 introduce a new intended use and do not raise different questions of safety and effectiveness when used as labeled. In addition, the minor technological differences between the Eko CORE

and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Eko CORE is as safe and effective as the predicate device. Thus, the Eko CORE is substantially equivalent.

Table1. Comparison with Predicate Devices

Parameters	**Eko Electronic Stethoscope System (OTC)**	**Eko Electronic Stethoscope System (Rx) - K151319**	**Tyto Stethoscope (OTC)- K181612**
Indications for Use	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 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.	The Eko Electronic Stethoscope System is intended to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. Eko is intended for use on pediatric and adult patients. It can electronically amplify, filter and transfer sounds to the accompanying mobile application for storage and sharing. It can used to record heart sounds and cardiac 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 Tyto Stethoscope is an electronic stethoscope that enables transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto Stethoscope is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.
Standards Met General Safety EMC Safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11
Device Classification	DQD: Electronic stethoscope	DQD: Electronic stethoscope	DQD: Electronic stethoscope
Prescribed	OTC	Rx	OTC

Parameters	Eko Electronic Stethoscope System (OTC)	Eko Electronic Stethoscope System (Rx) - K151319	Tyto Stethoscope (OTC)- K181612
Classification	Class II	Class II	Class II
Stethoscope Type	Attachment to an analog stethoscope (Core)	Attachment to an analog stethoscope (Core)	Stand-alone electronic stethoscope
User Interface	On/Off Power button Volume adjustment LED status indicator Mobile App	On/Off Power button Volume adjustment LED status indicator Mobile App	On/Off Power button Volume adjustment LED screen Mobile App
Analog/ Digital Interoperability	Yes	Yes	No
Connectivity	Bluetooth®	Bluetooth®	Wi-Fi
Sound Amplification	Yes	Yes	No
Record and Playback Sounds	Yes	Yes	Yes
Data Transfer to Compatible Computing platform	Yes	Yes	Yes