October 20, 2022

HomeDiagnostic LLC
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K220099
Trade/Device Name: eClinic Stethopod
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: October 4, 2022
Received: October 7, 2022

Dear Dave Yungvirt:

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,

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)*
K220099

Device Name
eClinic Stethopod

Indications for Use *(Describe)*
eClinic Stethopod is an Electronic Stethoscope. It converts patient auscultation sound (heart, lungs, bowel, arteries, and veins) into audio signal and transmits it to clinicians by clinically defined virtual appointment methods.
It is intended to be used by professional users in a clinical environment or by lay users in a nonclinical or clinical environment to assist remote healthcare professionals' physical assessment. The device is not intended for self-diagnosis. eClinic Stethopod is intended for patients or customers who are 2 years and older. It is for both prescription use and over the counter use.

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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K220099

510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR §807.92.

5.1 Applicant's Information

Name: HomeDiagnostic LLC
Address: 3160 De La Cruz Blvd Suite 100

Phone: 18669764038

Contact Person: Jian Gong
Email: info@eclinicdx.com
Preparation Date: 18 Oct 2022

5.2 Device Name

Product/Trade Name:	eClinic Stethopod (K220099)
Common Name:	Stethoscope
Classification Name:	Electronic Stethoscope
Regulatory Class:	Class II
Regulatory Number:	21 CFR870.1875
Product Code:	DQD

5.3 Legally Marketed Predicate Device

The predicate device for eClinic Stethopod is legally marketed Eko Core (K200776).

5.4 Device Description

5.4.1 Device Identification

eClinic Stethopod is an electronic stethoscope that is designed to be used with virtual communication systems for telehealth. It provides patient auscultation sounds for clinicians during virtual appointments while maintaining communication between clinicians and patients.

5.4.2 Device Characteristics

The eClinic Stethopod is a passive electromechanical device. It converts physiological sounds into audio signals through a microphone. It further processes the signal through passive electronics for noise reduction and then transmits the real time data to clinically defined communication applications that connect patients and clinicians.

5.4.3 Environment of Use

The eClinic Stethopod is used during physical assessment. The environment of use could be anywhere where physical assessment is done, for example non-clinical environment or healthcare facilities.

5.4.4 Brief Description of the Device

eClinic Stethopod has a chest piece to pick up acoustic signal, a handle housing electronics that converts acoustic signal to audio signal and a cable to connect with communication devices. eClinic Stethopod needs to be connected to a communication device to achieve its intended use. There are two accessories: Apple ear pod and Apple adapter (lighting to 3.5 mm jack).

5.4.5 Materials of Use

eClinic Stethopod is not intended to have direct contact to body fluid. It is intended to contact human intact skin for a very short period. The eClinic Stethopod parts that contact the skin are composed of biocompatible materials and compliance to ISO 10993-Part 1 Biological Evaluation of Medical Devices.

5.4.6 Essential Performance Characteristics

The essential performance characteristics of the eClinic Stethopod are listed in Table 1.

Table 1: eClinic Stethopod Essential Performance Characteristics

Feature	Specification
Chest Piece	Single Cup Chest piece
Chest Piece Diameter	48 mm
Chest Piece Ring	Anti-Chill silicone
Frequency Range	20-2000Hz
Weight	<250g
Compatible Software	iOS 13 or later, Android 8 and above, Zoom 5.4.3 and above
Compatible Devices	iPhone 6 or later, iPad Pro, iPad Mini, iPad 2 or later; iPod touch 4th generation; Android 8.0 and above

5.5 Intended Use

eClinic Stethopod is an Electronic Stethoscope. It converts patient auscultation sound (heart, lungs, bowel, arteries, and veins) into audio signal and transmits it to clinicians by clinically defined virtual appointment methods.
It is intended to be used by professional users in a clinical environment or by lay users in a nonclinical or clinical environment to assist remote healthcare professionals' physical assessment. The device is not intended for self-diagnosis.
eClinic Stethopod is intended for patients or customers who are 2 years and older. It is for both prescription use and over the counter use.

The predicate device is legally marketed Eko Core (K200776) manufactured by Eko Devices Inc.

Product/Trade Name:	Eko Core
Common Name:	Stethoscope
Classification Name:	Electronic Stethoscope
Regulatory Class:	Class II
Regulatory Number:	21 CFR870.1875
Product Code:	DQD

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. It is intended for use on pediatric

and adult patients. It 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.

eClinic Stethopod is equivalent to the predicate device in:

- Both are electronic stethoscope;
- Both convert auscultation sound into audio signal and transmits it to clinicians;
- Both are used to be part of a physical assessment remotely;
- Both could be used by lay users in non-clinical environment or clinical environment;
  The transmitted auscultation sound will be used by professionals sitting remotely to assist diagnoses.
- Both are not used for self-diagnostics.

The intended use of eClinic Stethopod is the same to the predicate devices for remote physical assessment. The statement variation between eClinic Stethopod and predicate device is not critical to the intended use of the device. The differences do not affect the safety and effectiveness of the device.

5.6 Comparison of Technological Characteristics with the Predicate Device

The principal operation of the eClinic Stethopod is the same to the predicate devices. Acoustic physiology sound is picked up by microphone and converted into audio signal. Then it is transmitted to advanced communication tools to be heard remotely by clinicians.

The following technological characteristics of the eClinic Stethopod is equivalent to the predicate devices:

- Use mechanical chest piece to collect physiological sounds;
- Use microphone and electronics to digitalize the physiological sounds;
- Use electronics to reduce noise;
- Use advanced communication tools (smart phones and operation system IOS or Android);

The following technological characteristics of the eClinic Stethopod is different to the predicate device:

- eClinic Stethopod sends data via a cable to smartphones, tablets, or computers. The predicate device uses RF wireless transmission.
- eClinic Stethopod works with phone calls or virtual appointment systems defined by clinics or hospitals. The recommended video system is Zoom. For the predicate device, its own App is needed to function.

  The implementation differences such as wire/wireless transmission, and virtual appointment system software/ device's own App, do not impact the device's safety and efficacy for the intended use of the device.

5.7 Performance data

The performance of the eClinic Stethpod described in this submission was evaluated according to the quality system regulation (21 CFR §820). Design verification and design validation tests confirmed that all design requirements were met and that the device functions as intended.

Based on design verification test, eClinic Stethopod is equivalent to the predicate device on sound rhythm, heartbeat rate, frequency spectrum and signal to noise ratio for its intended application.

eClinic stethopod sound quality and usability are further evaluated by clinicians and volunteers in design validation. It is concluded eClinc stethopod sound quality through phone calls and Zoom is acceptable and it is easy to use.

5.8 Conclusions

The eClinic Stethopod's intended use, and technological characteristic are equivalent to those of the predicate device. Differences in implementation between the eClinic Stehopod and the predicate do not raise any concerns in regard to safety or effectiveness. It is concluded that the proposed eClinic Stethopod is substantially equivalent to the predicate device within the meaning of the Medical Device Amendments Act of 1976.

Table 2. Comparison with the Predicate Device

Elements of Comparison	eClinic Stethopod (K220099)	Eko CORE (K200776)
General		
Regulatory Class	Class II	Class II
Classification name	Electronic Stethoscope	Electronic Stethoscope
Regulation Number	21 CFR870.1875	21 CFR870.1875
Product Code	DQD	DQD
Manufacturer	HomeDiagnostic LLC	Eko Devices, Inc
FDA Clearance	Pending	510K cleared (K200776)
Indications for Use	eClinic Stethopod is an Electronic Stethoscope. It converts patient auscultation sound (heart, lungs, bowel, arteries, and veins) into audio signal and transmits it to clinicians by clinically defined virtual appointment methods. It is intended to be used by professional users in a clinical environment or by lay users in a nonclinical or clinical environment to assist remote healthcare professionals' physical assessment. The device is not intended for self-diagnosis. eClinic Stethopod is intended for patients or customers who are 2 years and older. It is for both prescription use and over the counter 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.
Patient Group	Pediatric and adult patients	Pediatric and adult patients
Type of Users	Patients and Health-care professional	Patients and Health-care professional
Use Environment	Nonclinical or Clinical settings	Nonclinical or Clinical settings
Clinical Conditions	Heart, Lung and other human body sounds	Heart, Lung and other human body sounds
Prescribed	OTC and Rx	OTC and Rx
Characteristics		

Principles of Operation	Microphone and electronics for converting physiology sound to audio signal, reducing noise, and sending data to clinically defined virtual appointment systems through advanced communication tools, such as smartphones, tablets or computers.	Eko CORE is a modified version of the previously cleared predicate device (K151319). The principles of operation is the same as K151319: Electronic stethoscope that gives sound amplification and audio transmission to a smartphone
Stethoscope Type	Stand-alone electronic stethoscope with chest pieces sourced from analog stethoscope	Attachment to an analog stethoscope (Core)
Real time sound	Real time auscultation sound	Real time auscultation sound
Record and Playback Sounds	No	Yes
Communication	Patient and clinician real time communication.	Patient and clinician real time communication.
Compatibility (Chest piece)	Chest Piece is part of eClinic Stethopods	Littmann 3M Cardiology II/III -WelchAllyn Harvey Elite -ADC601 lines of analog stethoscopes
Compatibility App	Direct phone calls on iOS 6 and above or Android 8 and above; Zoom 5.4.3 and above	Eko App
Technical Equivalence		
User Interface	• 3.5mm headphone jack • Mobile App (Clinical defined)	• On/Off Power button • Volume adjustment • LED status indicator • Mobile App
Analog/Digital Interoperability	Yes	Yes
Connectivity	Cable	Bluetooth
Sound Amplification	No	Yes
Data Transfer to compatible computing platforms	Yes	Yes
Energy Source	Power derived from connected digital device. No additional battery needed.	Lithium Ion Battery
Compatible Devices	IOS and Android smartphones, Computers	IOS and Android smartphones, Computers
Frequency range	20Hz -2kHz	20Hz to 2kHz
Standards	N/A	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11