April 10, 2024

Lapsi Health Holding B.V
% Orly Maor
Consultant
25 Sirkin Street
Kfar Saba, 4442157
Israel

Re: K233313
Trade/Device Name: Keikku Electronic stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: September 29, 2023
Received: September 29, 2023

Dear Orly Maor:

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,

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

Indications for Use Statement

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)*

K233313

Device Name

Keikku Electronic Stethoscope

Indications for Use *(Describe)*

The Keikku is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation data of the patient (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on a network can listen to the auscultation data of a patient on site or at a different location on the network. The Keikku is intended for use on pediatric and adult patients. The Keikku 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional Premarket Notification Submission – 510(k)
Keikku Electronic Stethoscope
510(k) Number K233313

Date Prepared: April 5, 2024

I. SUBMITTER

Lapsi Health Holding B.V.
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II. DEVICE

Name of Device: Keikku Electronic Stethoscope
Common or Usual Name: Keikku Electronic Stethoscope
Classification Name: 21 CFR 870.1875; Stethoscope, Electronic
Regulatory Class: II
Product Code: DQD.

III. PREDICATE DEVICE

Lapsi Health Holding B.V. believes that the Keikku Electronic Stethoscope is substantially equivalent to the following predicate device:

- Eko CORE manufactured by Eko Devices, Inc. cleared under K200776, Classification name Electronic stethoscope, Product code: DQD, Regulation: 21 CFR 870.1875

The following device is used as a reference device:

- 3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3200 manufactured by Eko Devices, Inc. cleared under K083903, Classification name Electronic stethoscope, Product code: DQD, Regulation: 21 CFR 870.1875

IV. DEVICE DESCRIPTION

The Keikku (Rx) is a digital stethoscope device designed for use by health care professionals in clinical settings and by lay users in non-clinical environments under healthcare provider supervision. The Keikku electronically amplifies, filters and transfers body sounds through the accompanying mobile application and is used for storage, sharing and transmitting the data for

telemedicine use. It also enables lay users, under supervision from a healthcare provider, to listen to their body sounds (lungs, heart, arteries, veins, gastrointestinal tract, etc.), record and share it with their physicians during telehealth sessions.
The Keikku consists of two primary components:

1. The Keikku device is an electronic stethoscope. The Keikku device is used for recording audio, converting it to digital data, and transmitting the data to a mobile device via Bluetooth®. It includes volume adjustment via rotation, tap feature for starting and ending the recording, and an LED light indicator for indicating the status of the device.
2. The Keikku App. The app captures audio data from the Keikku device and provides data visualization and annotation, secure data storage, audio playback, and sharing features. These features enable a healthcare professional to monitor patients, seek second opinions from a specialist or use the device for telemedicine use.

V. INDICATIONS FOR USE

The Keikku is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation data of the patient (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on a network can listen to the auscultation data of a patient on site or at a different location on the network. The Keikku is intended for use on pediatric and adult patients. The Keikku 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Keikku Electronic Stethoscope has the same intended use as the predicate device. Its indications for use are identical to that of the predicate device.
The Keikku Electronic Stethoscope has similar technological characteristics as the predicate device as demonstrated in the table below:

Specification/ Feature	**Keikku electronic stethoscope K_____**	**Eko CORE K200776**	**Littmann 3200 K083903**	**Comparison**
Regulation number and Product Code	DQD , 870.1875	DQD , 870.1875	DQD, 870.1875	Same
Intended use	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope	Same
Indications for use	The Keikku is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation data of the patient (heart, lungs, bowel,	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and	The 3M™ Littmann® Electronic Stethoscope Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of	Same as EKO core

Specification/ Feature	Keikku electronic stethoscope K_____	Eko CORE K200776	Littmann 3200 K083903	Comparison
	arteries, and veins), whereby a clinician at one location on network can listen to the auscultation data of a patient on site or at a different location on the network. The Keikku is intended for use on pediatric and adult patients. The Keikku 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.	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.	sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selective frequency ranges. It can be used on any person undergoing a physical assessment	
Intended patient population	Adults and pediatric	Adults and pediatric	Adults and pediatric	Same
Prescribed	Rx	OTC	Rx	Same as the reference
Chest-piece	Yes	Yes	Yes	Same
Sound Processing	Digital signal processing	Digital signal processing	Digital signal processing	Same
Amplification	Increases the volume to reach a constant value, up to 42dB	Increases the volume up to 40x amplification	Up to 28dB acoustic gain, equivalent to 24 times amplification	Same as the predicate
Auscultation position guide	Yes, using the video session	Yes, using the Software Application	NA	Similar
Signal Transmission	Wireless Network, Bluetooth	Wireless Network, Bluetooth	NA	Same
Display	Smartphone (iOS or Android) device	Smartphone (iOS or Android)	liquid crystal display (LCD)	Same as predicate
Form Factor	Wireless headsets	Similar to traditional stethoscope + optional wireless headsets	Similar to traditional stethoscope	Same as predicate

Specification/ Feature	Keikku electronic stethoscope K_____	Eko CORE K200776	Littmann 3200 K083903	Comparison
Environment of use	Professional users in a clinical environment or by lay users in a nonclinical environment.	Professional users in a clinical environment or by lay users in a nonclinical environment.	Professional users in a clinical environment	Same as predicate
Application	Real time	Real time	Real time	Same
Bluetooth	5 LE	4.2 LE	Class 2 Bluetooth	Same
Diaphragm	Silicon rubber	Epoxy/Fiberglass	Polyurethane coated silicon	Different however has no impact on performance as was determined by testing.
Pickup sensor	MEMS microphone	MEMS microphone	Unknown	Same as EKO core
Frequency Response	Extended: 50-800Hz	Bell: 20 - 200Hz. Diaphragm: 100 - 500Hz Extended: 50 - 500Hz	Bell: 20-200Hz Diaphragm: 100-500Hz Extended range: 50-500 Hz.	Similar
Power Source	Rechargeable battery	Rechargeable battery	AA battery	Same as EKO core
IP	IP44	IP22	IPX4 (chest piece only)	Similar
Signal input method	Sound waves collected via a digital microphone	Toggle between analog and amplified listening modes	Sound waves collected via a transducer	Similar
Signal storage	Keikku app (iOS and Android)	EKO software (iOS and Android)	via Bluetooth link to a PC	Same as EKO core

VII. PERFORMANCE DATA

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

Biocompatibility

Biocompatibility evaluation in compliance with ISO 10993-1 was evaluated.

- **Cleaning and Disinfection Testing**
  Cleaning and disinfection validation were performed.
  All tests were successfully completed.

- **Performance Testing**
  Performance testing included comparison testing of the Keikku Electronic Stethoscope to its predicate and reference device. The main purpose of this test was to verify the Keikku's performance is similar to that of its predicate and reference devices, Eko Core and 3M Littmann electronic stethoscope, in terms of audio frequency and NSR response.
  The test passed and met the predefined acceptance criteria.

- **Software Validation**
  The Keiiku Electronic Stethoscope is categorized as Enhanced. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

- **Electrical Safely and EMC**
  Electrical Safety per IEC 60601-1, Electromagnetic compatibility (EMC) per IEC 60601-1-2 and usability per IEC 60601-1-6 were conducted on the Keikku Electronic Stethoscope.
  The tests passed.

- **Usability Evaluation**
  Usability study was conducted with passing results.

VIII. CONCLUSION

The Keikku Electronic Stethoscope was determined to be substantially equivalent to the predicate and reference device.