November 24, 2020

Chip Ideas Electronics S.L
Bernardo Trillo
Regulatory Affairs Manager
Calle Alfareria 3 B
Burjasot, Valencia 46100
Spain

Re: K201742
Trade/Device Name: eKuore One Wireless Electronic Interface for stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: October 26, 2020
Received: October 30, 2020

Dear Bernardo Trillo:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201742

Device Name
eKuore One Wireless electronic interface for stethoscope

Indications for Use *(Describe)*
The eKuore One Wireless electronic interface for stethoscope 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. eKuore One Wireless is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to the accompanying mobile software application.

It can be 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.

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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eKuore One Wireless
Electronic Interface for Stethoscope
510(k) Premarket Notification

Section 5 – 510(k) Summary

SUBMITTER

Submitter name: Chip Ideas Electronics, S.L.
Submitter address: C/ Alfarería 3 B. 46100
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SPAIN

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Date Prepared: November 23th, 2020

DEVICE

Device Trade Name: eKuore One Wireless electronic interface for stethoscope
Common Name: ELECTRONIC STETHOSCOPE
Regulation Name: ELECTRONIC STETHOSCOPE
Regulatory Class: Class II
Product Code: DQD
Regulation Number: 870.1875

PREDICATE DEVICE

Predicate Device (S): Eko Electronic Stethoscope System, K151319

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Section 5 – 510(k) Summary

I. DEVICE DESCRIPTION

The equipment consists of a stethoscope attachment, which will let the sound flow through the stethoscope´s tube, so the stethoscope can continue working as usual, and the sound will be collected by a little hole in the piece, where a microphone will be placed. Then, this piece will be covered by a plastic case. A Bluetooth module is placed for a wireless transition of the data to a mobile (Android/IOS) or tablet.
The eKuore One Wireless electronic interface for stethoscope gets the power supply from an internal rechargeable battery.

The application allows the user to visualize audio streaming received from the stethoscope. The connection is established between the smartphone application and the selected device, and after this event, the selected device starts to stream audio to the smartphone application.
The application also allows the user to record the current audio streaming, storing it in the internal storage of the Android/iOS device. The recordings can be viewed, shared and deleted after that.

The application does not store or collect any personal data of the users or patients. The only generated artifacts generated with the use of the application, the auscultations stored in the internal storage of the Android/iOS device, can only be identified by its name, which is a combination of the time and date when the auscultation was performed, which is insufficient to identify uniquely a patient or gets its personal information.

II. INDICATIONS FOR USE

The eKuore One Wireless electronic interface for stethoscope is indicated to be used as a part of a physical assessment of a patient by healthcare professionals for diagnostic decision support in clinical settings. eKuore One Wireless is indicated for use on pediatric and adult patients. It can electronically filter and transfer sounds to the accompanying mobile software application.

It can be 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.

Section 5 – 510(k) Summary

III. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The electronic stethoscopes are mainly used on auscultation in the detection of cardiac, respiratory sounds and check other internal organs. These types of devices are used to digitize the data of the auscultation into a mobile device.

In the establishment of substantial equivalence, eKuore One Wireless electronic interface for stethoscopes compared to the predicate device K181882 eKuore One electronic interface for stethoscope and the reference device K151319 Eko Electronic Stethoscope System:

Elements of comparison	eKuore One Wireless electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Reference device)	Comparison
Regulatory data			
Regulatory Class	Class II	Class II	Identical to predicate device
Device Classification name	Electronic Stethoscope	Electronic Stethoscope	Identical to predicate device
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	Identical to predicate device
Classification Product code	DQD	DQD	Identical to predicate device
Manufacturer	Chip Ideas Electronics, S.L.	Eko Devices, Inc.	-
FDA Clearance	Pending	K151319	-
USE			
Intended use	The eKuore One Wireless electronic interface for stethoscope 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. eKuore One Wireless is indicated for use on pediatric and adult patients. It can electronically filter and transfer sounds to the accompanying mobile	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.	Similar to predicate device. Predicate device also amplify sound.

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eKuore One Wireless
Electronic Interface for Stethoscope
510(k) Premarket Notification

Section 5 – 510(k) Summary

Elements of comparison	eKuore One Wireless electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Reference device)	Comparison
	software application. It can be 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.	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.	
Characteristics			
Principles of operation	The device consists in a microphone and some electronics for their digitalization and codification to a standard format, and sending via wireless (Bluetooth) to smartphones and tablets.	Dispositive introduced in an acoustic stethoscope and gives sound amplification and audio transmission to a smartphone via Bluetooth that allows the user to open and playback sounds in a mobile application on compatible iOS smartphones and tablets.	Similar to predicate device. Both acquire and transmit sound to a mobile app.
Clinical conditions	Human body sounds related	Human body sounds related	Identical to predicate device
Use	Electronic stethoscope	Electronic stethoscope	Identical to predicate device
Compatibility	-Littmann 3M Cardiology III/IV -Littmann 3M classic II/III	-Littmann 3M Cardiology II/III -Welch Allyn Harvey Elite -ADC601 lines of analog stethoscopes	Similar to predicate device. Both devices are compatible with stethoscopes Littmann 3M Cardiology III
Prescription/OTC	Prescription use	Prescription use	Identical to predicate device
Intended for Direct Connection to Patient	No	No	Identical to predicate device
Use environment	Clinical	Clinical	Identical to predicate device
Type of users	Health-care personnel	Health-care personnel	Identical to predicate device
Target population	All types of patients	All types of patients	Identical to predicate device
Cleaning & Maintenance	Before clean eKuore One Wireless, please detach it	The stethoscope and CORE should be cleaned between	Identical to predicate device

Section 5 – 510(k) Summary

Elements of comparison	eKuore One Wireless electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Reference device)	Comparison
	of the stethoscope. It can be easily cleaned by suing an alcohol wipe. Cleaning of stethoscope should be done between each patient use. Is not necessary to clean eKuore One Wireless for each use with the same patient.	eachpatient use. All cleaning instructions pertaining to the originalstethoscope apply. Under normal conditions it is unnecessary to remove CORE fromthe stethoscope tubing for cleaning. All external parts of thehardware can be cleaned with 70% isopropyl alcohol wipes.	
Technical equivalence			
Sound track transfer function	Yes	Yes	Identical to predicate device
Signal transmission for visualization	Bluetooth transmission to compatible smartphones/tablets	Bluetooth transmission to compatible smartphones/tablets	Identical to predicate device
Energy Source	Rechargeable Lithium Ion Battery	Rechargeable Lithium Ion Battery	Identical to predicate device
System required	Android and iOS	Android and iOS	Identical to predicate device
Hardware and software platforms	Mobile devices or tablets	Mobile devices or tablets	Identical to predicate device
Connections	Micro USB connector only to charge internal battery of the device	Micro USB connector only to charge internal battery of the device	Identical to predicate device
Frequency range	20 Hz to 2 KHz	20 Hz to 2 kHz	Identical to predicate device
Signal Input Method	Sound was collected via a Transducer. MEMS	Sound waves collected via a Transducer. Electro micro-phone	Identical to predicate device
Audio Output Method	Earbuds and 3.5mm Jack when connected with smartphone/tablets	Earbuds and 3.5mm Jack when connected with smartphone/tablets	Identical to predicate device
Signal Storage	Allows signal storage depending on technical features (capacity,…) of connected device (smartphone or tablet).	Allows signal storage depending on technical features (capacity,…) of connected device (smartphone or tablet).	Identical to predicate device
Performance requirements	Temp range: -20ºC to +45ºC Humidity range: 0% to 90%	The operating range is 10ºC to 40ºC, and 0% to 90% relative humidity	Similar to predicate device.
Biological Equivalence			
Materials	•Cover: ABS and EPDM	Body: ABS (Acrylonitrile	Similar to predicate

Section 5 – 510(k) Summary

Elements of comparison	eKuore One Wireless electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Reference device)	Comparison
	(ethylene propylene diene monomer) •Pushbutton: PMMA (para-Methoxy-N-methylamphetamine) •Gasket: EPDM	Butadiene Styrene).	device
Contact with human tissues or body fluids	Does not contact patient´s body. Attached stethoscope does.	Does not contact patient´s body. Attached stethoscope does.	Identical to predicate device
Sterility	Sterility considerations are not applicable	Sterility considerations are not applicable	Identical to predicate device

Table 05-1. Substantial Equivalence Comparison – eKuore One Wireless electronic interface for stethoscope and Predicate Device EKo Electronic Stethoscope System K151319

Information provided in these 510(k) submissions shows that eKuore One Wireless Electronic Interface for Stethoscope is substantially equivalent to the predicate device Eko Electronic Stethoscope System cleared under K151319 in terms of intended use, indications for use, compatibility, and technological characteristics. There are no new questions of safety or effectiveness.

Summary discussion of non-clinical data:

The proposed device has been designed, developed, tested, verified and validated according to documented procedures and specific protocols in line with the following FDA guidance documents:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- General Principles of Software Validation
- Guidance for Premarket Submissions for Management of Cybersecurity in Medical Devices
- Postmarket Management of Cybersecurity in Medical Devices
- Radio Frequency Wireless Technology in Medical Devices

General requirements for basic safety standard requirements for medical electrical equipment test have been successfully completed following standard of IEC 60601-1:2008 and IEC 60601-1-2:2015
Integration verification and validation testing have been successfully completed following standard IEC 62304:2006/AC:2008
Usability testing requirements have been evaluated and successfully met standards

ISO 62366:2008+A1:2015 and IEC 60601-1-6:2010.
Design and development included identification, evaluation and control of potential hazards as per standard ISO 14971:2012.

Summary discussion of clinical data:
Non-clinical test data are submitted to support this premarket notification and to establish the decision concerning adequate safety and performance of the subject device.

IV. CONCLUSIONS

We believe the intended use, indication for use, principle of operation and technical characteristics of the eKuore One Wireless electronic interface for stethoscope are the same as the intended use, indication for use, principle of operation and technical characteristics of the predicate device.

We did not use new technology in this system, so those differences between our system and its predicate do not affect the safety and performance.

- General information of the propose and predicate device are the same.
- Intended use and indication/principle of operations of the propose device and predicate device are the same.
- There are minimum differences in the technological characteristics of the propose device and the predicate device.

Based on the information provided in this premarket notification, Chip Ideas Electronics S.L., concludes that eKuore One Wireless electronic interface for stethoscope does not suppose any new or increased risk compared with the predicate device, we conclude that eKuore One Wireless is substantially equivalent to the listed legally marketed predicate device.