March 27, 2019

Chip Ideas Electronics S.L
Bernardo Plaza Trillo
Chief Operating Officer
C/ Clariano 8, Entresuelo B
Valencia, 46021 SPAIN

Re: K181882
Trade/Device Name: eKuore One electronic interface for stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: February 4, 2019
Received: February 8, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -S
2019.03.27 14:42:30 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K181882

Device Name
eKuore One electronic interface for stethoscope

Indications for Use *(Describe)*
The eKuore One 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 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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SUBMITTER

Submitter name: Chip Ideas Electronics, S.L.
Submitter address: C/ Clariano 8, Entresuelo B.
46021 Valencia
SPAIN

Contact person: Bernardo Plaza Trillo
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Date Prepared: 2018-03-16

DEVICE

Device Trade Name: eKuore One 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

I. DEVICE DESCRIPTION

eKuore One is a system formed by eKuore One device and eKuore ONE App. The main purpose of eKuore One device is to digitalize auscultation sounds. The main purpose of eKuore ONE App is to get the acoustic signal from eKuore One device through point to point connection via USB OTG cable. The data transmission via the USB OTG cable provides high data integrity.

eKuore ONE App displays the acoustic signal as a phonogram in real time and allow user to make recordings for later use.

eKuore ONE App detects the eKuore One device automatically once the USB OTG cable is connected.

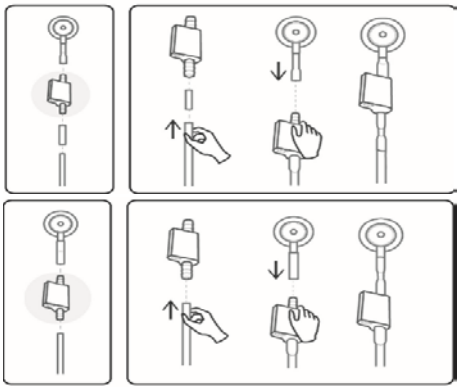
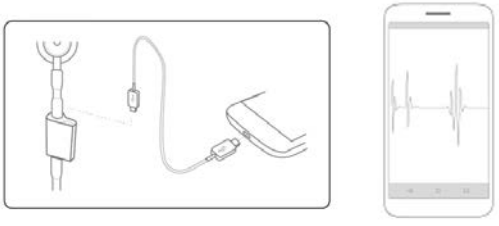
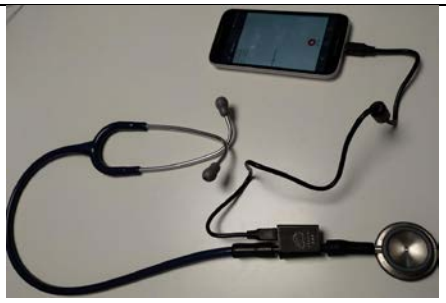
Once eKuore One device is detected, the application identifies the device and make a connection. Once connected, the application goes to the monitor screen where the phonogram is shown in real time, the data represented in the eKuore ONE App is not processes prior to display.

In the monitor screen, there is a record button. When pressed, it starts a recording with a duration of 15 seconds. Recordings are stored in *.wav file format in the internal memory of the connected smartphone/tablet. At the end of the recording process, the application asks the user for a “PatientID” and “Position” only to conform the recording name. The idea is to help the user in the later handling of the recordings.

eKuore ONE App has a recording management screen where it is possible to play, remove and edit a recording. The edition is only for the “PatientID” and “Position”. The audio data of one recording can’t be modified either shared.

eKuore ONE App has an internal security process to remove any recording with incorrect name format or without the required duration.

Furthermore, eKuore ONE App has a tutorial to help the user and one “About App” screen where access to support is available.

Equipment description	
	eKuore One the main piece. Is the part which is attached to the stethoscope.
	eKuore One the main piece, internal view.
	eKuore One preparation into the tubing adaptors to the stethoscope. The first pictogram is for attachment with Littmann Cardiology stethoscopes The second one is for attachment with Littmann Classic stethoscopes
	eKuore One installed into the stethoscope and USB cable to display the digital sound to the mobile device.
	eKuore One real view of complete installation.

II. INDICATIONS FOR USE

The eKuore One 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 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.

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 electronic interface for stethoscopes compared to the predicate device K151319 Eko Electronic Stethoscope System:

Elements of comparison	eKuore One electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Predicate device)	Comparison
Regulatory data			
Regulatory Class	Class II	Class II	Identical to predicate 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
Product code	DQD	DQD	Identical to predicate device
Manufacturer	Chip Ideas Electronics, S.L.	Eko Devices, Inc.	-
FDA Clearance	Pending	510(k) cleared: K151319	-

Elements of comparison	eKuore One electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Predicate device)	Comparison
USE			
Indications for use	The eKuore One 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 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.	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 Indications for Use statement for the eKuore One is identical to the predicate device.
Characteristics			**Comparison**
Principles of operation	The device consists in a microphone and some electronics for their digitalization and codification to a standard format, and sending via USB cable 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 with the following gaps: - Amplification vs only digitalization - RF transmission (Bluetooth) vs USB cable - IOS & Android vs Android

Elements of comparison	eKuore One electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Predicate device)	Comparison
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 II/III -Littmann 3M classic II	-Littmann 3M Cardiology II/III -WelchAllyn Harvey Elite -ADC601 lines of analog stethoscopes	Similar to predicate device
Prescription/OTC	Prescription use	Prescription use	Identical to predicate device
Intended for Direct Connection to Patient	NO	NO	Identical to predicate device
Use environment	Hospitals	Hospitals	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
Technical equivalence			
Sound track transfer function	Yes	Yes	Identical to predicate device
Signal transmission for visualization	Wired transmission to compatible smartphones	Bluetooth transmission to compatible smartphones	Different from predicate device
Energy Source	Provided by smartphone via USB cable	Lithium Ion Battery	Different from predicate device
System required	Android device	Android device and Apple, Inc	Similar to predicate device
Hardware and software platforms	Mobile devices or tables	Mobile devices or tablets	Identical to predicate device
Connections	Micro USB conector to communicate with the mobile phone	Micro USB conector only to charge internal battery of the device	Different from 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 Trasnducer. 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	Earbuds and 3.5mm Jack when connected with smartphone	Identical to predicate device

Elements of comparison	eKuore One electronic interface for stethoscope (Candidate Device)	Eko electronic stethoscope system. (Predicate device)	Comparison
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: -10ºC to +40ºC Humidity range: 0% to 90%	The operating range is -10ºC to 40ºC, and 0% to 90% relative humidity	Identical to predicate device
Biological Equivalence			
Materials	Body: ABS (Acrylonitrile Butadiene Styrene)	Body: ABS (Acrylonitrile Butadiene Styrene).	Identical to predicate 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	Not intended to be sterilized	Not intended to be sterilized	Identical to predicate device

Table 1. Substantial Equivalence Comparison – eKuore One electronic interface for stethoscope and Predicate Device K151319

As seen in the table above, most elements of comparison are identical between both proposed and predicate devices. The most relevant similarities of eKuore One electronic interface for stethoscope and Eko Electronic Stethoscope System include the following technological elements:

- Compatible Stethoscopes:
  Both are designed to work with 3M Littmann Cardiology II/III stethoscopes. They may also work with many other brands models.

- Digital signal processor:
  Both the eKuore One and Eko Core use the stethoscope attached to the device to filter internal organ sounds from the patient.

- System configuration:
  Both are closed systems providing a mobile app software that displayed the signal from the internal organ sounds into a mobile device.

- Frequency range
  The eKuore One and Eko Core use the same frequency range that is the place where the cardiac and pulmonary sounds are located.

- Signal storage:
  The eKuore One and Eko Core allow recording auscultation sounds in the application software.

- Hardware and software platform:
  The eKuore One and Eko Core are compatible with mobile devices software and they can be used on mobile and tablet app software.

The following technological differences exist between the subject and predicate devices:

- Principle of operation:
  The eKuore One electronic digitalize the internal organ sounds and is intended to not alter the auscultation sounds captured by the stethoscope attached whilst the equivalent device Eko Core Electronic Stethoscope system amplify the organ sounds being able to alter the recording auscultation sounds

- Signal transmission for visualization:
  The eKuore One electronic interface for stethoscope not require enable Bluetooth pairing with the device to transmit sounds whereas the Eko Electronic Stethoscope system used Bluetooth to transmit signal sounds into a mobile device.

- Energy Source:
  The eKuore One obtain the energy source by smarthphone via USB cable whereas the Eko Core used Lithium Ion Battery.

- Connections:
  The connectios of eKuore One use a micro USB to communicate with the mobile phone while Eko Core need micro USB connector to charge internal battery of the device.

eKuore One electronic interface for stethoscope is a simpler variant of the Eko

electronic stethoscope system predicate design and with same indications for use. Technological differences as established above have been addressed in the different bench tests performed on the proposed device to provide data to support that they do not affect the safety and effectiveness of the device relative to the predicate. In conclusion eKuore One has similar intended uses as the predicate device and has very similar technological characteristics.

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 requirements for basic safety standard requirements for medical electrical equipment test have been successfully complete following standard of AAMI ANSI 60601-1:2005 and A1:2012 and IEC 60601-1-2 Edition 4: 2014-02
Integration verification and validation testing have been successfully complete following standard IEC 62304:2015.
Usability testing requirements have been evaluated and successfully met as per standards AAMI ANSI IEC 62366:2007.
Design and development included identification, evaluation and control of potential hazards as per standard ISO 14971:2007.
An acoustic performance comparison between eKuore One electronic interface for stethoscope and Eko Electronic Stethoscope System has been performed. Device signal acquisition accuracy and acoustic transmission disturbance has been evaluated and successfully, presenting both devices with similar acoustic characteristics.

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 predicate device.

IV. CONCLUSIONS

Based on the information provided in this premarket notification, Chip Ideas Electronics S.L., concludes that eKuore One electronic interface for stethoscope is substantially equivalent to the listed legally marketed predicate device.