October 30, 2020

Chip Ideas Electronics S.L.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K203007
Trade/Device Name: eKuore Pro Series
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: September 28, 2020
Received: October 1, 2020

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,

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)*

K203007

Device Name
eKuore Pro Series

Indications for Use *(Describe)*

The eKuore Pro Series 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 Pro Series 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

ekuore

Section 5 – 510(k) Summary

SUBMITTER

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

Registration Number: 3017140534
Owner Operator Number: 10075275

Contact person: Bernardo Plaza Trillo
Phone: +34 640742454
e-mail: bernardo.plaza@ekuore.com

Date Prepared: 2020-10-26

DEVICE

Device Trade Name: eKuore Pro Series
Common Name: ELECTRONIC STETHOSCOPE
Regulation Name: ELECTRONIC STETHOSCOPE
Regulatory Class: Class II
Product Code: DQD
Regulation Number: 870.1875

PREDICATE DEVICE

Predicate Device (S): 3M Littmann Electronic Stethoscope Model 3200 (K083903)

5.1 DEVICE DESCRIPTION

eKuore Pro Series is formed by eKuore Pro Series device and eKuore Pro App.

The eKuore Pro Series device introduce three different models:

- **eKuore Pro**, the basic version of the stethoscope.
- **eKuore Pro Amplified**, that has a higher sound amplification designed for people with hearing problems

The main purpose of eKuore Pro Series device is the detection and amplification of heart, lung, arteries, veins and internal sounds using selective frequency organ ranges. eKuore Pro and eKuore Pro Amplified creates a WLAN access point, to which the client is able to connect via Wi-Fi with smartphones and tablets, to send the data acquired during auscultation to the eKuore Pro App.

The design of eKuore Pro Series lets the user change the chestpiece attached between different sizes depend on the patient to be auscultated.

The main purpose of the eKuore Pro Series App is to get the acoustic signals from the eKuore Pro Series WLAN access point. Once the device is turn on, a new Wi-Fi signal could be detected by the smartphone/tablet, the signal name contains the last 6 digits of the serial number of the device for its identification.

After the connection, the eKuore Pro App displays the acoustic signal as a phonogram in real time, in the monitor screen there is a record button. When it is pressed the recording start, there is defined a record maximum duration of 30 seconds, it could be changed on the App configuration to 60, 90 or 120 seconds. To stop the record the recording button must be pressed again. Recordings are stored in *.wav file format in the internal memory of the connected smartphone/tablet, each recording is stored named with the date and time of the moment of the record.

eKuore Pro App has a management screen where it is possible to play, remove and edit a recording. Only the length and the name of the record file could be edited. Also, the eKuore Pro App lets the user share the records.

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

Section 5 – 510(k) Summary

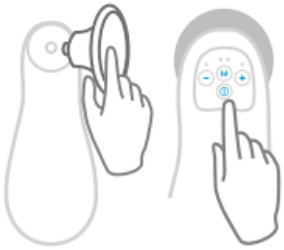
Equipment description	
	eKuore Pro Series main piece with the chestpiece attached.
	To use the eKure Pro Series devices the chestpice must be attached and turn it on, as is shown in the pictogram. There are three models of chestpiece depend on the patient to be auscultated. S, M or L from neonatal to adults patients.
	eKuore Pro Series device is connected via Wi-Fi with eKuore Pro App installed in the smartphone/tablet. Then the ekuore Pro App shows the phonogram in real time.
	eKuore Pro Series product packaging.

Table 5.1 Equipment Description

The following table shows the difference and similarities of each model:

Section 5 – 510(k) Summary

Characterictic	EP0002	EP0099
Form	Same for both models	
Design	Same for both models	
Material	Same for both models	
Function	For healthcare professionals	For healthcare professionals that needs increased volume
Connectivity	Create an WLAN access point	Create an WLAN access point
Volume control / gain	5 steps, 2 dB of difference between levels	5 steps, 2 dB of difference between levels with an offset of +6db
Energy Supply	Same for both models	
Software	Compatible with eKuore Pro APP.	Compatible with eKuore Pro APP.
Firmware	eKuore Pro FW v1.10.07	eKuore Pro FW v1.10.07
DSP configuration	v00.00.08	v00.00.58
Hardware	Same for both models	

Table 5.2 - eKuore Pro Series models comparison table

5.2 INDICATIONS FOR USE

The eKuore Pro Series 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 Pro Series 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.

5.3 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 Pro Series compared to the predicate device K083903, 3M Littmann Electronic Stethoscope Model 320

Section 5 – 510(k) Summary

Elements of comparison	eKuore Pro Series (New Device)		3M Littmann Electronic Stethoscope Model 3200 (Predicate device)	Comparison
	eKuore Pro	eKuore Pro Amplified		
Regulatory Class	Class II	Class II	Class II	Identical to predicate device
Classification name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope	Identical to predicate device
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	21 CFR 870.1875	Identical to predicate device
Product code	DQD	DQD	DQD	Identical to predicate device
Manufacturer	Chip Ideas Electronics, SL.	Chip Ideas Electronics, SL.	3M Company	-
FDA Clearance	Pending	Pending	510(k) cleared: K083903	-
USE				
Indications for use	The eKuore Pro Series 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 Pro Series 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 eKuore Pro Series 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 Pro Series 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 3MTM Littmann® Electronic stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment	Similar to predicate device
Characteristics				
Principles of operation	The device picks up sounds from a patient's body. This sound is filtered, amplified and sent it to the user through earbuds, also it can be sent	The device picks up sounds from a patient's body. This sound is filtered, amplified + 6dB offset and sent it to the user through earbuds, also it can	Model 3200 electronic stethoscope picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user	Similar to predicate device

Section 5 – 510(k) Summary

Elements of comparison	eKuore Pro Series (New Device)		3M Littmann Electronic Stethoscope Model 3200 (Predicate device)	Comparison
	eKuore Pro	eKuore Pro Amplified		
	via WiFi to compatible smartphones and tablets.	be sent via WiFi to compatible smartphones and tablets.	through a binaural headset. Also, can be sent via Bluetooth to compatible devices.	
Clinical conditions	Human body sounds related	Human body sounds related	Human body sounds related	Identical to predicate device
Use	Electronic stethoscope	Electronic stethoscope	Electronic stethoscope	Identical to predicate device
Prescription/O.T.C.	Prescription use	Prescription use	Prescription use	Identical to predicate device
Intended for Direct Connection to Patient	YES	YES	YES	Identical to predicate device
Use environment	Clinical settings	Clinical settings	Clinical settings	Identical to predicate device
Type of users	Health-care personnel	Health-care personnel with hearing difficulties	Health-care personnel	Similar to predicate device. eKuore Pro Amplified is designed for Health-care personnel with hearing difficulties due to increased amplification
Target population	Pediatric and adult patients	Pediatric and adult patients	Adult, pediatric and infants	Similar to predicate device
Cleaning & Maintenance	When the power supply is off, the entire plastic surface can be cleaned sliding an alcohol pad. Excess fluid during cleaning can cause leakage of moisture on internal components. Clean the stethoscope from patient to patient.	When the power supply is off, the entire plastic surface can be cleaned sliding an alcohol pad. Excess fluid during cleaning can cause leakage of moisture on internal components. Clean the stethoscope from patient to patient	Cleaning of stethoscope should be done between each patient use. Cleaning the Chestpiece Under normal conditions, it is unnecessary to remove the diaphragm for cleaning. The diaphragm can easily be cleaned by using an alcohol wipe.	Identical to predicate device
Technical equivalence				
Sound track transfer function	Yes	Yes	Yes	Identical to predicate device
Signal transmission for visualization	Wireless transmission to compatible smartphones/ tablet via WiFi	Wireless transmission to compatible smartphones/ tablet via WiFi	Wireless transmission to compatible smartphones/tablets via Bluetooth	Similar to predicate device.
Energy Source	Lithium-Ion Battery	Lithium-Ion Battery	AA Alkaline, Lithium or NiMH battery	Similar to predicate device.
System required	Android device and Apple, Inc	Android device and Apple, Inc	PC/Mac	Different to predicate device
Hardware and	Mobile devices or tables	Mobile devices or tables	PC/Mac	Different to predicate device

ekuore

Section 5 – 510(k) Summary

Elements of comparison	eKuore Pro Series (New Device)		3M Littmann Electronic Stethoscope Model 3200 (Predicate device)	Comparison
	eKuore Pro	eKuore Pro Amplified		
software platforms				
Connections	Micro USB connector only to charge the internal battery of the device	Micro USB connector only to charge the internal battery of the device	None	Different to predicate device
Filter frequency range	• Heart (50-150 Hz) • Lung (50-500 Hz) • Extended (40-600 Hz)	• Heart (50-150 Hz) • Lung (50-500 Hz) • Extended (40-600 Hz)	• Bell (20-200 Hz) • Diaphragm (100-500 Hz) • Extended Range (50-500 Hz)	Similar to predicate device
Wireless data transmission	Audio	Audio	Audio	Identical to predicate device
Signal Input Method	Sound waves collected via a Transducer. Microelectro-mechanical microphone	Sound waves collected via a Transducer. Microelectro-mechanical microphone	Sound waves collected via a Transducer. Electret microphone	Identical to predicate device
Audio Output Method	Earbuds connected with the device through the 3.5mm Jack directly to the eKuore device or from the smartphone/tablet audio outputs	Earbuds connected with the device through the 3.5mm Jack directly to the eKuore device or from the smartphone/tablet audio outputs	Binaural headset	Different to predicate device
Signal Storage	Depend on Smartphone/tablet internal memory, eKuore Pro App lets the user record 30, 60, 90 or 120 seconds. eKuore Pro Series devices does not stored data.	Depend on Smartphone/tablet internal memory, eKuore Pro App lets the user record 30, 60, 90 or 120 seconds. eKuore Pro Series devices does not stored data.	Up to 12 separate 30-second sound tracks for later playback in internal storage.	Different to predicate device
Performance requirements	Temp range: 0ºC to +40ºC Humidity range: 15% to 93%	Temp range: 0ºC to +40ºC	Temp range: -30°C to 40°C Humidity range: 15% to 93%	Similar to predicate device
Biological Equivalence				
Body material	ABS (Acrylonitrile Butadiene Styrene)	ABS (Acrylonitrile Butadiene Styrene)	ABS	Identical to predicate device
Diaphragm material	Membrane: Epoxy and Fiberglass Membrane's ring: PVC	Membrane: Epoxy and Fiberglass Membrane's ring: PVC	Polyurethane coated silicone	Different to predicate device
Contact with human tissues or body fluids	The chestpiece is in contact with patients' skin.	The chestpiece is in contact with patients' skin.	The chestpiece is in contact with patients' skin.	Identical to predicate device
Sterility	Not intended to be sterilized	Not intended to be sterilized	Not intended to be sterilized	Identical to predicate device

Table 5.3. Substantial Equivalence Comparison – eKuore Pro Series and Predicate Device K083903

Section 5 – 510(k) Summary

Information provided in these 510(k) submissions shows that eKuore Pro Series is substantially equivalent to the predicate device 3M Littmann Electronic Stethoscope Model 3200 cleared under K083903 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 requirements for basic safety standard requirements for medical electrical equipment test have been successfully complete following standard of AAMI ANSI ES 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 Pro Series and 3M Littmann electronic stethoscope model 3200 has been performed. Device signal acquisition accuracy and acoustic transmission disturbance has been evaluated and successfully, presenting in all 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.

5.4 CONCLUSIONS

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