May 26, 2022

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

Re: K211779
Trade/Device Name: eKuore Stethoscope Touch
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 25, 2021
Received: December 13, 2022

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,

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)*
K211779

Device Name
eKuore Stethoscope Touch

Indications for Use *(Describe)*

The eKuore Stethoscope Touch 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.

The eKuore Stethoscope Touch is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to a compatible 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 Stethoscope Touch
510(k) Premarket Notification

Section 5 – 510(k) Summary

SUBMITTER

Submitter name: Chip Ideas Electronics, S.L.
Submitter address: C/ Alfarería 3 B.
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Registration Number: 3017140534
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Date Prepared: 2022-01-11

DEVICE

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

PREDICATE DEVICE

Predicate Device (S): eKuore Pro Series (K203007)

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Section 5 – 510(k) Summary

5.1 DEVICE DESCRIPTION

eKuore Stethoscope Touch is formed by eKuore Stethoscope Touch device, eKuore Medical Devices App and eKuore Touch Android Engine.

The eKuore Stethoscope Touch device introduces three different models:

- **ES001** is the basic version of the electronic stethoscope for general purposes.
- **ES002** is an electronic stethoscope designed for people with hearing problems and enable hearing aids connection.
- **ES003** is an electronic stethoscope that can connect to third-party software using an Android Library.

The primary purpose of the eKuore Stethoscope Touch device is to detect and amplify heart, lung, arteries, veins, and internal sounds using selective frequency organ ranges.

The design of eKuore Stethoscope Touch lets the user change the chestpiece attached between different sizes depending on the patient to be auscultated.

The primary purpose of the eKuore Medical Devices App is to get the acoustic signals from the eKuore Stethoscope Touch device. Once the device is turned on, the smartphone/tablet could detect a Bluetooth device.

After the connection, the eKuore Medical Devices App displays the acoustic signal as a phonogram in real-time, on the monitor screen, there is a record button. When it is pressed, the recording start, a record maximum duration of 30 seconds is defined. 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 Medical Devices 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 Medical Devices App lets the user share the records.

eKuore Touch Android Engine enable third party companies to connect eKuore Stethoscope Touch model ES003 to obtain the audio from the device and use it in their own software. Audio is transmitted without modifications or processing.

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510(k) Premarket Notification

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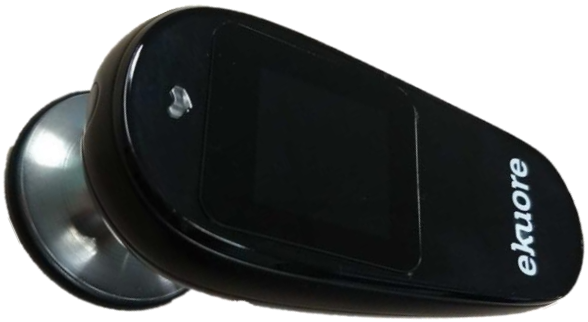
Equipment description	
	eKuore Stethoscope Touch device with the chestpiece attached. There are three models of chestpiece that depend on the patient to be auscultated. S, M or L from neonatal to adults patients

Table 5.1 Equipment Description

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

Specification	ES001	ES002	ES003	Note:
Model	ES001	ES002	ES003	
Basic UDI-DI	8437021515ES001T9	8437021515ES002TB	8437021515ES003TD	
Dimensions	132*55*35mm			
Screen	1,54 OLED with resistive touchscreen			
Device lifetime from the date of manufacture	10 years			Manufacturing date included in labeling
Frequency response	20Hz to 8KHz			
Signal to Noise Ratio	62.5dB			
Data representation	16-24 bits			
Environmental range	Temperature: 10ºC to +40ºC Humidity: 0-90%			
Maximum audio delay	50ms			
Internal memory	Up to 10 recordings			
Battery	1400mAH rechargeable LiPo Battery			
Functionalities:	USB-C audio output 3 selective filters Android and iOS compatible	USB-C audio output 3 selective filters Bluetooth audio devices compatible	USB-C audio output 3 selective filters Compatible with eKuore ES Android Engine library	
GMDN	13754			
Weight	75g			
Power supply Battery charger	1400mAH rechargeable LiPo battery Not included. Use USB-C cable provided with a 5V DC charger			EN 60601-1 compliant
Data interface	USB-C Audio	USB-C Audio	USB-C Audio	
Wireless communication	Bluetooth	Bluetooth	Bluetooth/WiFi	ES001 Bluetooth for app communication. ES002 Bluetooth for

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Specification	ES001	ES002	ES003	Note:
				the audio stream. ES0003 Bluetooth and WiFi for the audio stream
Use combined with	iOS / Android App Interchangeable chestpieces	A2DP Bluetooth receivers Interchangeable chestpieces	Android Engine library Interchangeable chestpieces	
Manufacturer	CHIP IDEAS ELECTRONICS SL			

Table 5.*2* - Comparison table of eKuore Stethoscope Touch models

5.2 INDICATIONS FOR USE

The eKuore Stethoscope Touch 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.

The eKuore Stethoscope Touch is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to a compatible 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 to detect 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 or computers.

In the establishment of substantial equivalence, eKuore Stethoscope Touch compared to the predicate device (K203007) eKuore Pro Series.

eKuore Stethoscope Touch is the evolution of CHIP IDEAS ELECTRONICS SL, electronic stethoscopes.

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Section 5 – 510(k) Summary

Elements of comparison	eKuore Stethoscope Touch (Candidate Device)			eKuore Pro Series (Predicate Device)	Comparison
	ES001	ES002	ES003		
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, SL.			Chip Ideas Electronics, SL.	Identical to predicate device
FDA Clearance	K211779 Pending			K203007	-
USE					
Indications for use	The eKuore Stethoscope Touch 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. The eKuore Stethoscope Touch is intended for use on pediatric and adult patients. It can electronically filter and transfer sounds to a compatible 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.	Similar to predicate device with the following gap: Predicate Device: connects only to mobile apps. Canidate device can connects to mobile apps but also other devices.
CHARACTERISTICS					
Principles of operation	The device consists in a microphone and some electronics for their digitalization, amplification, and codification to a standard format, and sending using wireless technology to compatible devices and software.			The device consists in a microphone and some electronics for their digitalization, amplification, and codification to a standard format, and sending via WiFi to	Similar to predicate device with the following gaps: . WiFi transmission vs WiFi and Bluetooth transmission

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Elements of comparison	eKuore Stethoscope Touch (Candidate Device)			eKuore Pro Series (Predicate Device)	Comparison
	ES001	ES002	ES003		
				smartphones and tablets.	. IOS & Android App vs multiple devices
Clinical conditions	Human body sounds related			Human body sounds related	Identical to predicate device
Use	Electronic stethoscope			Electronic stethoscope	Identical to predicate device
Compatibility	Android and iOS devices	Bluetooth receivers	Third party Android projects	Android and iOS devices	Predicate device is an electronic stethoscope that can send audio to iOS and Android devices, candidate device can also transfer sound to other compatible systems.
Prescription/O.T.C.	Prescription use			Prescription use	Identical to predicate device
Intended for Direct Connection to Patient	YES			YES	Identical to predicate device
Use environment	Clinical settings			Clinical settings	Identical to predicate device
Type of users	Healthcare personnel	Healthcare personnel with hearing aids	Healthcare personnel	Healthcare personnel	Similar to predicate device. ES002 is designed to transfer sound to Bluetooth hearing aids
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	Wireless transmission to compatible systems via WiFi and Bluetooth			Wireless transmission to compatible smartphones/tablet via WiFi	Different from predicate device, candidate device can also transfer sound using Bluetooth connectivity
Device control	1.4' touch screen			Touching buttons	Different to predicate device.
Energy Source	Lithium-Ion Battery			Lithium-Ion Battery	Identical to predicate device
System required	Android and iOS	Bluetooth	Third party	Android and iOS devices	Predicate device can send audio to iOS and

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Section 5 – 510(k) Summary

Elements of comparison	eKuore Stethoscope Touch (Candidate Device)			eKuore Pro Series (Predicate Device)	Comparison
	ES001	ES002	ES003		
	devices	receivers	Android projects		Android devices, candidate device can also transfer sound to other compatible systems.
Connections	Micro USB connector to charge the internal battery of the device and audio output			Micro USB connector only to charge the internal battery of the device 3.5mm Jack audio output	Different to predicate device. Candidate outputs the audio using USB-C connector.
Frequency range	40 Hz to 600 Hz			40 Hz to 600 Hz	Identical to predicate device
Signal Input Method	Sound waves collected via a Transducer. Electro micro-phone			Sound waves collected via a Transducer. Electro micro-phone	Identical to predicate device
Audio Output Method	USB-C			3.5mm Jack	Different to predicate device. Candidate outputs the audio using USB-C connector.
Signal Storage	Allows signal storage depending on technical features (capacity, OS) of connected device (smartphone or tablet). Internal memory with 10 recording slots			Allows signal storage depending on technical features (capacity, OS) of connected device (smartphone or tablet).	Different to predicate device. Candidate has internal memory for up to 10 auscultations
Performance requirements	Temp range: 10ºC to +40ºC Humidity range: 15% to 93%			Temp range: -20ºC to +45ºC Humidity range: 15% to 93%	Different to predicate device
BIOLOGICAL EQUIVALENCE					
Materials	Body: ABS (Acrylonitrile Butadiene Styrene) and PMMA (Polymethyl methacrylate) Chestpiece base: AISI 303 (stainless steel). Chestpiece ring and membrane: PVC.			Body: ABS (Acrylonitrile Butadiene Styrene) Chestpiece base: AISI 303 (stainless steel). Chestpiece ring and membrane: PVC.	Body material similar to predicate device. Identical materials for chestpiece and parts
Contact with human tissues or body fluids	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	Identical to predicate device

Table 5.3. Substantial Equivalence Comparison – eKuore Stethoscope Touch and Predicate Device K203007

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Section 5 – 510(k) Summary

Information provided in these 510(k) submissions shows that eKuore Stethoscope Touch is substantially equivalent to the predicate device eKuore Pro Series under K203007 in terms of indications for use, compatibility and technological characteristics. There are no new questions of the safety or effectiveness of the device when used as labeled.

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 completed 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 14971:2019.
An acoustic performance comparison between the eKuore Stethoscope Touch and the eKuore Pro Series has been performed. Device signal acquisition accuracy and acoustic transmission disturbance have been evaluated 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 Stethoscope Touch is substantially equivalent to the listed legally marketed predicate device.

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