May 23, 2022

Shanghai Hulu Devices Co., Ltd
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K220470
Trade/Device Name: Smart Wireless Stethoscope (Model: STEMO300, STEMO500, STEMO700)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: April 22, 2022
Received: April 25, 2022

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,

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)*
K220470

Device Name
Smart Wireless Stethoscope (Model: STEMO300, STEMO500, STEMO700)

Indications for Use *(Describe)*
The Smart Wireless Stethoscope enables amplification, filtering, and transmission of auscultation sounds from the heart, lungs, bowel, arteries, and veins. A medical professional at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The device is intended for use on pediatric and adult patients. The device 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5

510(k) Summary

510(k) Summary

5.1 General Information

Submitter	Shanghai Hulu Devices Co., Ltd
Address	No. 509 Caobao Road, Room 101-2 Bld 9, Xuhui District, Shanghai, China
Contact Person:	Junfeng Zhao Phone: 0086-18621892190 Email: zhaoap@hotmail.com
Date Prepared:	Dec 31, 2021
Device Name:	Smart Wireless Stethoscope
Models	STEMO300, STEMO500, STEMO700
Common Name:	Electronic Stethoscope
Classification:	II
Regulation Number	870.1875
Regulation Name:	Electronic Stethoscope
Product Code:	DQD

5.2 Predicate Device

510(k) Number	Comparison
K200776	Intended use, prescription or OTC use, technology, major functions such as auscultation, recording, amplification, mobile application support and livestream.

5.3 Device Description

The proposed smart wireless stethoscope is made of a Bluetooth® stethoscope and a companion medical mobile application that runs on a smartphone or a tablet. The stethoscope picks human body sounds with an acoustic structure that is similar to the chest piece of a traditional stethoscope. Then the sounds are converted to electrical audio signals by a microphone in the device. The electrical audio signals are further processed and transmitted through Bluetooth® protocol. The device has three models STEMO300, STEMO500 and STEMO700. All the three models can work with the companion app running on a smartphone or tablet. When they work this way, the stethoscope transmits audio to the app and the sounds can be further processed in the app. The app provides functions such as amplification, visualization, filtering, recording, sharing, etc. STEMO500 and STEMO700 have an ambient noise cancelling option while STEMO300 not. Unlike STEMO300 or STEMO500, STEMO700 has an option to directly transmit audio to paired Bluetooth earphones. Here is a comparison of these three models.

	Comparison Item	STEMO300	STEMO500	STEMO700
1	App support	Work with the same companion app		
2	Hardware Operation	Similar way to switch on/off; similar notification light		
3	Noise cancelling option	NO	YES	YES
4	Option to directly transmit audio to Bluetooth® earphones	NO	NO	YES

5.4 Indications for Use

The Smart Wireless Stethoscope enables amplification, filtering, and transmission of auscultation sounds from the heart, lungs, bowel, arteries, and veins. A medical professional at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The device is intended for use on pediatric and adult patients. The device 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.

5.5 Technology Characteristics

The Proposed smart wireless stethoscope has substantially equivalent indications for use and very similar technology characteristics as its predicate devices. Here is a comparison on the major technology characteristics between the current device and the preliminary predicate device.

Item	Current Device	Predicate Device	Comparison
Classification	Class II	Class II	Same
Regulation	21 CFR 870.1875	21 CFR 870.1875	Same
Product code	DQD	DQD	Same
Regulation name	Electronic Stethoscope	Electronic Stethoscope	Same
Indications for use	The Smart Wireless Stethoscope enables amplification, filtering, and transmission of auscultation sounds from the heart, lungs, bowel, arteries, and veins. A medical professional at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The device is intended for use on	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and 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	Substantially Equivalent

	pediatric and adult patients. The device 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.	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.	
Prescription or OTC use	OTC	OTC	Same
Transducer	Microphone	Microphone	Same
Frequency range	20-2000Hz	20-2000Hz	Same
Sample rate	4000Hz	4000Hz	Same
Software platform	Compatible with Android and iOS devices	Compatible with Android and iOS devices	Same
Transmission over Bluetooth®	YES	YES	Same
Listening through the companion app	YES. The sounds can be heard via earphones connected to a phone or a tablet that runs the companion app.	YES. The sounds can be heard via earphones connected to a phone or a tablet that runs the companion app.	Same
Direct listening	Model STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset.	Eko CORE allows direct listening to sounds in real time through the device's attached earpieces.	Substantially Equivalent. Direct listening is an optional feature that an electronic stethoscope can have.
Recording and Playback	Not on the device itself, but with its companion app.	Not on the device itself, but with its companion app.	Same
Sound amplification	YES	YES	Same
Phonocardiogram	Displayed in the companion app.	Displayed in the companion app.	Same
Power source	Rechargeable Lithium-ion polymer battery	Rechargeable Lithium-ion polymer battery	Same
Connections	Micro USB connector only to charge internal battery of the device	Micro USB connector only to charge internal battery of the device	
Ambient noise	Model STEMO300 does	Has ambient noise	Substantially

cancelling	not have ambient noise cancelling feature. Model STEMO500 and STEMO700 have ambient noise cancelling feature that can be turned on/off in its companion app.	cancelling feature. It can be turned on/off in its companion app.	Equivalent. Ambient noise cancelling is an optional feature that an electronic stethoscope can have.
Livestream	The livestream function transfers stethoscope sounds over IP network.	The livestream function transfers stethoscope sounds over IP network.	Substantially Equivalent.

Overall, the proposed device has the same or similar technology characteristics of the predicate device.

5.6 Performance Data

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

5.6.1 Biocompatibility Testing

The biocompatibility evaluation for this device was conducted in accordance with the FDA Guidance "Use of International Standard ISO10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" and the International Standard ISO 10993-1 Fourth Edition 2009-10-15, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)], as recognized by FDA. The testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

5.6.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on this device. The system complies with the IEC 60601-1 and IEC 60601-1-11 standard for safety, IEC 60601-1-2 for EMC, and ANSI IEEE C63.27-2017 and AAMI TIR69:2017/(R2020) for wireless co-existence.

5.6.3 Software Verification and Validation Testing

The software of this device is verified and validated according to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

5.6.4 Clinical Test

No clinical test is submitted in this 510(k).

5.7 Conclusion

Based on the technological characteristics of the devices and the intended use, we can conclude that the proposed smart wireless stethoscope and its predicate devices are substantially equivalent. The differences do not raise any new issues of safety or effectiveness.