

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 <u>Federal Register</u>.

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-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">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)
Sinat wheress stemoscope (woder, STEMO500, STEMO500)
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.
Tuno of Lina (Salast one or both, as applicable)
Type of Use (Select one or both, as applicable)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Over-The-Counter Use (21 CFR 801 Subpart C)

Prescription Use (Part 21 CFR 801 Subpart D)

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."

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®	NO	NO	YES
	earphones			

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. Prescription or office office is not intended for self-diagnosis. Prescription or OTC OTC OTC Same Prequency range 20-2000Hz 20-2000Hz Same Frequency range 20-2000Hz 4000Hz Same Software Compatible with Android and iOS devices are tablet that runs the companion app. Direct listening YES. The sounds can be heard via carphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening function. STEMO500 do not have direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound YES. The sounds can be heard via carphone or a tablet that uns the companion app. Sound YES. The sounds can be heard via carphones at ablet that runs the companion app. Sound YES. The sounds can be heard via carphones at ablet that runs the companion app. Power source Section of the device itself, but with its companion app. Power source Rechargeable Lithium-ion polymer battery Of the device of the device Ambient noise Model STEMO300 does Has ambient noise Substantially				
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 OTC OTC Same Prequency range 20-2000Hz 20-2000Hz Same Frequency range 20-2000Hz 4000Hz Same Software Compatible with Android and iOS devices Orneus direct listening function. First listening Model STEMO300 and STEMO500 do not have direct listening function and allows direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback With its companion app. Sound YES Connections Microphone Microphone Same Transmission over Bluetooth® Office Issening function. STEMO700 has direct listening in real time using a Bluetooth® enabled headset. Recording and Playback With its companion app. Diver source Rechargeable Lithium-ion polymer battery of the device o		pediatric and adult patients.	pediatric and adult patients.	
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 Prescription or OTC use Prequency range Sample rate 4000Hz Compatible with Android platform and iOS devices Authoridation app. Listening through the companion app Direct listening Bileutooth® enabled inter listening function STEMO500 has direct list		The device is intended to	The Eko CORE is intended	
environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis. Prescription or OTC use Prescription or OTC use Transducer Microphone Microphone Microphone Microphone Microphone Microphone Same Prequency range 20-2000Hz Same 4000Hz Software Compatible with Android and iOS devices Transmission over Bluetooth® Listening the companion app. Direct listening Model STEMO300 and 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. Recording and Playback Recording and mapplification Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device oTC OTC OTC OTC Same Microphone Same AllowoHz Sam				
in a nonclinical environment. The device is not intended for self-diagnosis. Prescription or OTC Use Transducer Microphone Microphone Same Frequency range 20-2000Hz 20-2000Hz Same Software Compatible with Android and iOS devices Transmission over Bluetooth® Listening Hurtough the companion app Companion app Companion app Companion app Companion app Companion and allows direct listening function and allows direct listening in real time using a Bluetooth® Playback With its companion app. Recording and Playback With its companion app. Power source Rechargeable Lithium-ion polymer battery of the device of t		users in a clinical	users in a clinical	
environment. The device is not intended for self-diagnosis. Prescription or OTC OTC OTC Same Prequency range Sample rate 4000Hz Compatible with Android and iOS devices Transmission over Bluetooth® Listening through the companion app Direct listening Model STEMO500 do not have direct listening function allows direct listening a Bluetooth® crabled headset. Recording and Playback Recording and amplification Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device of		environment or by lay users	environment or by lay users	
not intended for self-diagnosis. Prescription or OTC Use Transducer Microphone Microphone Same Frequency range 20-2000Hz 20-2000Hz Same Sample rate 4000Hz 4000Hz Same Software Compatible with Android and iOS devices and iOS devices Transmission over Bluetooth® Listening Hard via earphones connected to a phone or a tablet that runs the companion app. 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. Recording and Not on the device itself, but with its companion app. Sound YES YES YES Same YES. The sounds can be heard via earphones connected to a phone or a tablet that runs the companion app. Elistening function and allows direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Not on the device itself, but with its companion app. Sound YES YES YES Same Power source Rechargeable Lithium-ion polymer battery of the device Micro USB connector only to charge internal battery of the device OTC OTC OTC OTC OTC OTC Same Microphone Same AndoOHz Same Obsplayed in the companion app. Sourd Micro USB connector only to charge internal battery of the device Of the device		in a nonclinical	in a nonclinical	
Prescription or OTC use Prescription or OTC use Transducer Microphone Microphone Same Frequency range 20-2000Hz 20-2000Hz Same Sample rate 4000Hz 3000Hz Same Software Compatible with Android and iOS devices Arisemission over Bluetooth® Listening through the companion app. Direct listening Model STEMO300 and STEMO700 has direct listening function adllows direct listening in real time using a Bluetooth® cound allows direct listening in real time using a Bluetooth® vith is companion app. Recording and Playback with its companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device is consumer and source in the manual proposed in the companion app. Micro USB connector only to charge internal battery of the device is consumental battery of the device immension and incompanion app. Micro USB connector only to charge internal battery of the device immension in the doutice internal battery of the device on the device is charge internal battery of the device on the device is consumental battery on the device is consumental proportional intermal battery of the device on the device of the device on the device of the		environment. The device is	environment. The device is	
Prescription or OTC use Transducer Microphone Microphone Same		not intended for	not intended for	
Transducer Microphone Microphone Same Frequency range 20-2000Hz 20-2000Hz Same Sample rate 4000Hz 4000Hz Same Software platform and iOS devices Arising in real time using a Bluetooth® real time using a maplification Recording and Playback Recording and ploymer battery Power source Rechargeable Lithium-ion polymer battery Connections Model SC companion abundal contact of the device		self-diagnosis.	self-diagnosis.	
Transducer Microphone Microphone Same Frequency range 20-2000Hz 20-2000Hz Same Sample rate 4000Hz 4000Hz Same Software Occupatible with Android and iOS devices Transmission YES YES Same Listening herard via carphones connected to a phone or a tablet that runs the companion app. 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. Recording and Playback With its companion app. Sound Software Connections And Software Sounds can be heard via carphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback With its companion app. Sound YES YES YES Same Power source Rechargeable Lithium-ion polymer battery Onnections Micro USB connector only to charge internal battery of the device of	Prescription or	OTC	OTC	Same
Frequency range Sample rate 4000Hz 4000Hz 4000Hz Same Software Compatible with Android and iOS devices Transmission over Bluetooth® Listening through the companion app Direct listening Addel STEMO500 do not have direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback Recording and Phonocardiogram Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device Compatible with Android ad000Hz Compatible with Android and iOS devices Same Same Same Same Same YES. The sounds can be heard via carphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening to sounds in real time through the device's attached earpieces. Listening is an optional feature that an electronic stethoscope can have. Same Same YES Same Same YES Same Same Same Same And iOS devices YES. The sounds can be heard via carphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening to sounds in real time through the device's attached earpieces. Listening to sounds in real time through the device's attached earpieces. Direct listening is an optional feature that an electronic stethoscope can have. Same YES Same Same Power source Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device	OTC use			
Sample rate 4000Hz 4000Hz Same Software Compatible with Android and iOS devices arisesion over Bluetooth® Listening through the companion app. Direct listening Model STEMO300 and allows direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound Sound amplification Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Mage and iOS devices YES Compatible with Android and iOS devices YES. The sounds can be heard via earphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening function. STEMO700 has direct listening to sounds in real time through the device's attached earpieces. Istening function and allows direct listening in real time through the device's attached earpieces. Istening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. YES YES Same Same Same Same Companion app. Sound Sound Sound Sound Sound And Sound	Transducer	Microphone	Microphone	Same
Software platform and iOS devices and iOS devices YES Transmission over Bluetooth® Listening through the companion app Direct listening Mandel STEMO300 and STEMO500 do not have direct listening function and allows direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound Agent Model STEMO300 and STEMO500 do not have direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Displayed in the companion app. Sound Agent 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. Recording and Playback with its companion app. Sound Agent Model STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening in real time through the device's attached earpieces. It is the through the device it self, but with its companion app. Sound Agent Model STEMO300 and STEMO500 do not have direct listening in real time through the device itself, but with its companion app. Sound STEMO500 do not have direct listening in real time through the device itself, but with its companion app. Sound STEMO500 do not have direct listening in real time through the device itself, but with its companion app. Sound STEMO500 do not have direct listening in real time through the device itself, but with its companion app. Sound STEMO500 do not have direct listening in real time through the device itself, but with its companion app. Sound STEMO500 do not have direct listening in real time through the device itself, but with its companion app. Sound STEMO500 do not have direct listening in real time through the device itself, but with its companion	Frequency range	20-2000Hz	20-2000Hz	Same
platform and iOS devices Transmission over Bluetooth® Listening through the companion app Direct listening listening function and allows direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound amplification Phonocardiogram Possible Actions of the device of the	Sample rate	4000Hz	4000Hz	Same
Transmission over Bluetooth® Listening through the heard via earphones companion app companion app. Direct listening Model STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening in real time using a Bluetooth® enabled headset. Recording and Playback With its companion app. Recording and Playback With its companion app. Power source Rechargeable Lithium-ion polymer battery Connections Made STEMO3D can be heard via earphones connected to a phone or a tablet that runs the companion app. Same YES. The sounds can be heard via earphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening to sounds in real time through the device's attached earpieces. Iistening to sounds in real time through the device's attached earpieces. Iistening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. Sound Are Companion app. Power source Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device Micro USB connector only to charge internal battery of the device	Software	Compatible with Android	Compatible with Android	Same
Listening through the heard via earphones connected to a phone or a tablet that runs the companion app. Direct listening Model STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening in real time using a Bluetooth® enabled headset. Recording and Playback With its companion app. Sound Application Displayed in the companion app. Displayed intendents of the device itself, but with its companion app. Displayed in the companion app. Displayed intendents of the device itself, but with its companion app. Displayed intendents of the device itself, but with its companion app. Displayed in the companion app. Displayed in the companion app. Displayed intendents of the device itself, but with its companion app. Displayed in the companion app. Disp	platform	and iOS devices	and iOS devices	
Listening through the heard via earphones connected to a phone or a tablet that runs the companion app. Direct listening Model STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening in real time using a Bluetooth® enabled headset. Recording and Playback With its companion app. Recording and Playback With its companion app. Power source Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device vonnected to a phone or a tablet that runs the connected to a phone or a tablet that runs the tablet that runs the comnected to a phone or a tablet that runs the comnected to a phone or a tablet that runs the connected to a phone or a tablet that runs the comnected to a phone or a tablet that runs the companion app. Eko CORE allows direct listening in real time through the device's attached earpieces. Bek CORE allows direct listening to sounds in real time through the device's attached earpieces. Listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. YES Same Same	Transmission	YES	YES	Same
through the companion app connected to a phone or a tablet that runs the companion app. 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. Recording and Playback With its companion app. Recording and Playback With its companion app. Power source Rechargeable Lithium-ion polymer battery Model STEMO300 and STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening to sounds in real time through the device's attached earpieces. listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. YES Same Phonocardiogram Displayed in the companion app. Rechargeable Lithium-ion polymer battery Of the device Micro USB connector only to charge internal battery of the device of the device Connections Read via earphones connected to a phone or a tablet that runs the companion app. Eko CORE allows direct listenially listening to sounds in real time through the device's attached earpieces. listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. YES Same Same	over Bluetooth®			
companion app connected to a phone or a tablet that runs the companion app. 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. Recording and Playback Recording and Playback Phonocardiogram Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Model STEMO300 and tablet tablet that runs the companion app. Eko CORE allows direct listening to sounds in real time through the device's attached earpieces. Ilistening to sounds in real time through the device's attached earpieces. Ilistening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. YES YES Same Same Power source Rechargeable Lithium-ion polymer battery Of the device Micro USB connector only to charge internal battery of the device of the device	Listening	YES. The sounds can be	YES. The sounds can be	Same
tablet that runs the companion app. Direct listening Model STEMO300 and STEMO500 do not have direct listening function. STEMO700 has direct listening function and allows direct listening in real time through the device's attached earpieces. STEMO700 has direct listening in real time using a Bluetooth® enabled headset. Recording and Playback Not on the device itself, but with its companion app. Sound Application Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device STEMO700 has direct listening to sounds in real time through the device's attached earpieces. Direct listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. Same Same Same Same Same Companion app. Power source Micro USB connector only to charge internal battery of the device of the device	through the	heard via earphones	heard via earphones	
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. Recording and Playback Not on the device itself, but with its companion app. Sound amplification Phonocardiogram Plower source Rechargeable Lithium-ion polymer battery Connections Model STEMO300 and Eko CORE allows direct listenially Equivalent. Direct listening to sounds in real time through the device's attached earpieces. listening function and allows direct listening in real time using a an electronic stethoscope can have. Not on the device itself, but with its companion app. YES YES Same Same Power source Rechargeable Lithium-ion polymer battery Of the device Of the device Of the device Substantially Equivalent. Direct Stethoscope listening is an optional feature that an electronic stethoscope can have. Same Same Same Same Same Same Optional feature that an electronic stethoscope can have. Same Same Optional feature that an electronic stethoscope can have. Same Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same Optional feature that an electronic stethoscope can have. Same	companion app	connected to a phone or a	connected to a phone or a	
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. Recording and Playback Not on the device itself, but with its companion app. Sound Application Phonocardiogram Plower source Rechargeable Lithium-ion polymer battery Connections Model STEMO300 and STEMO500 do not have listening function. STEMO700 has direct time through the device's attached earpieces. listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. Same Same Same Power source Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device ORE Allows direct listening to sounds in real time through the device's listening is an optional feature that an electronic stethoscope can have. Same Same Same Same Same Companion app. Same Connections Micro USB connector only to charge internal battery of the device Of the device		tablet that runs the	tablet that runs the	
STEMO500 do not have direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound Amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device STEMO500 do not have listening to sounds in real time through the device's attached earpieces. Direct listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. Not on the device itself, but with its companion app. Power source Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device Micro USB connector only to charge internal battery of the device STEMO700 has direct time through the device's attached earpieces. Direct listening is an optional feature that an electronic stethoscope can have. Same Same Same Same Same		companion app.	companion app.	
direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback Not on the device itself, but with its companion app. Sound amplification Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device stethoscope can have. Not on the device itself, but with optional feature that an electronic stethoscope can have. Same Same Displayed in the companion app. Same Displayed in the companion app. Rechargeable Lithium-ion polymer battery of the device of the device	Direct listening	Model STEMO300 and	Eko CORE allows direct	Substantially
STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound Amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device internal battery and poptional attached earpieces. listening is an optional feature that an electronic stethoscope can have. Not on the device itself, but with its companion app. Same Power of the device of the device itself, but with its companion app. Same Same Same VES Same Same Same Connections Micro USB connector only to charge internal battery of the device of the device		STEMO500 do not have	listening to sounds in real	Equivalent.
listening function and allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device itsend fixed an electronic stethoscope can have. Not on the device itself, but with its companion app. YES YES Same Same Optional feature that an electronic stethoscope can have. Same Vith its companion app. Same Same Same Companion app. Rechargeable Lithium-ion polymer battery to charge internal battery of the device		direct listening function.	time through the device's	Direct
allows direct listening in real time using a Bluetooth® enabled headset. Recording and Playback with its companion app. Sound amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device an electronic stethoscope can have. Not on the device itself, but with its companion app. YES YES Same Same Power source Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device Not on the device itself, but with its companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device		STEMO700 has direct	attached earpieces.	listening is an
real time using a Bluetooth® enabled headset. Recording and Playback Not on the device itself, but with its companion app. Sound amplification Phonocardiogram Phonocardiogram Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device itself, but Not on the device itself, but with its companion app. Same Posame Same Displayed in the companion app. Rechargeable Lithium-ion polymer battery to charge internal battery of the device an electronic stethoscope can have. Same Same Same Power source Rechargeable Lithium-ion polymer battery to charge internal battery of the device		listening function and		optional
Bluetooth® enabled headset. Recording and Not on the device itself, but with its companion app. Sound amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device Bluetooth® enabled can have. Not on the device itself, but with its companion app. Same Same Same Same Same Same Same Same Same Conpanion app. Same		allows direct listening in		feature that
Recording and Not on the device itself, but with its companion app. Sound YES YES Same Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device Recording and Not on the device itself, but with its companion app. PYES YES Same Displayed in the companion app. Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device		real time using a		an electronic
Recording and Playback with its companion app. Sound YES YES Same Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device Not on the device itself, but with its companion app. PYES Same Displayed in the companion app. Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device Not on the device itself, but with its companion app. Same Same Companion app. Rechargeable Lithium-ion polymer battery for the device of the device		Bluetooth® enabled		stethoscope
Playback with its companion app. with its companion app. Sound YES YES Same amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device of the device		headset.		can have.
Sound amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device YES Same Same Companion app. Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device	Recording and	Not on the device itself, but	Not on the device itself, but	Same
amplification Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device Displayed in the companion app. Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device	Playback	with its companion app.	with its companion app.	
Phonocardiogram Displayed in the companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device Displayed in the companion app. Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device of the device	Sound	YES	YES	Same
companion app. Power source Rechargeable Lithium-ion polymer battery Connections Micro USB connector only to charge internal battery of the device companion app. Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device	amplification			
Power source Rechargeable Lithium-ion polymer battery polymer battery Connections Micro USB connector only to charge internal battery of the device Rechargeable Lithium-ion polymer battery Micro USB connector only to charge internal battery of the device	Phonocardiogram	Displayed in the	Displayed in the	Same
polymer battery polymer battery Connections Micro USB connector only to charge internal battery of the device polymer battery of the device polymer battery Micro USB connector only to charge internal battery of the device		companion app.	companion app.	
Connections Micro USB connector only to charge internal battery of the device Micro USB connector only to charge internal battery of the device	Power source	Rechargeable Lithium-ion	Rechargeable Lithium-ion	Same
to charge internal battery of the device to charge internal battery of the device		polymer battery	polymer battery	
of the device of the device	Connections	Micro USB connector only	Micro USB connector only	
		to charge internal battery	to charge internal battery	
Ambient noise Model STEMO300 does Has ambient noise Substantially		of the device	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.