



July 31, 2026

Shanghai Hulu Devices Co., Ltd.  
Junfeng Zhao  
# 525 N. Sichuan Rd.  
Suite 2706  
Shanghai, 200085  
China

Re: K261494

Trade/Device Name: Smart Wireless Stethoscope (STEMO310, STEMO710, STEMO720, and STEMO730)

Regulation Number: 21 CFR 870.1875

Regulation Name: Stethoscope

Regulatory Class: Class II

Product Code: DQD

Dated: July 8, 2026

Received: July 8, 2026

Dear Junfeng Zhao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**STEPHEN C. BROWNING -S**

CDR 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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261494

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Please provide the device trade name(s).

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Smart Wireless Stethoscope (STEMO310);  
Smart Wireless Stethoscope (STEMO710);  
Smart Wireless Stethoscope (STEMO720);  
Smart Wireless Stethoscope (STEMO730)

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)  
☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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## **510(k) Summary**

### **5.1 General Information**

|                   |                                                                           |
|-------------------|---------------------------------------------------------------------------|
| Submitter         | Shanghai Hulu Devices Co., Ltd                                            |
| Address           | No. 525 North Sichuan Road, Suite 2706, Hongkou District, Shanghai, China |
| Contact Person:   | Junfeng Zhao<br>Phone: 0086-18621892190<br>Email: zhaoap@hotmail.com      |
| Date Prepared:    | Jan 29, 2026                                                              |
| Device Name:      | Smart Wireless Stethoscope                                                |
| Models            | STEMO310, STEMO710, STEMO720, STEMO730                                    |
| 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                                                                                                                                                    |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| K220470       | 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 device are Bluetooth stethoscopes. The device has four models STEMO310, STEMO710, STEMO720 and STEMO730. STEMO310 is the upgrade version of the model STEMO300 of the predicate device. STEMO710, STEMO720 and STEMO730 are the upgrade version of the model STEMO700 of the predicate device. 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. All the four models can work with the mobile application of the predicate. When they work this way, the stethoscope transmits audio to the app and the sounds can be further processed in the app. All four models can output analog audio through their USB Type-C port via USB Audio Adapter Accessory Mode protocol. Unlike model STEMO310, models STEMO710, STEMO720 and STEMO730 have an option to directly transmit audio to

paired Bluetooth earphones. STEMO710, STEMO720 and STEMO730 have an ambient noise cancelling option while STEMO310 not. STEMO730 has an OLED display to show the device status and heart rate. Here is a comparison of these models.

|   | Comparison Item                                           | STEMO310                         | STEMO710 | STEMO720 | STEMO730 |
|---|-----------------------------------------------------------|----------------------------------|----------|----------|----------|
| 1 | App support                                               | Work with the same companion app |          |          |          |
| 2 | Hardware Operation                                        | Similar way to turn on/off       |          |          |          |
| 3 | Noise cancelling option                                   | NO                               | YES      | YES      | YES      |
| 4 | Option to directly transmit audio to Bluetooth® earphones | NO                               | YES      | YES      | YES      |
| 5 | OLED display                                              | NO                               | NO       | NO       | YES      |
| 6 | Analog audio output on the USB Type-C port                | YES                              | YES      | YES      | 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 | The Smart Wireless Stethoscope enables amplification, filtering, and | Same       |

|                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |      |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
|                                     | 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. | 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. |      |
| 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 STEMO310 does not have direct listening function. STEMO710, STEMO720 and STEMO730 have direct listening function and allows direct listening in real time using a Bluetooth® enabled                                                                                                                                                                                                                                                                                                                                  | Model STEMO300 does not have direct listening function. STEMO700 has direct listening function and allows direct listening in real time using a Bluetooth® enabled headset.                                                                                                                                                                                                                                                                                                                   | Same |

|                                                   |                                                                                                                                                                                      |                                                                                                                                                              |                                                                                                                 |
|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
|                                                   | headset.                                                                                                                                                                             |                                                                                                                                                              |                                                                                                                 |
| Sound amplification                               | YES                                                                                                                                                                                  | YES                                                                                                                                                          | Same                                                                                                            |
| Power source                                      | Rechargeable Lithium-ion polymer battery                                                                                                                                             | Rechargeable Lithium-ion polymer battery                                                                                                                     | Same                                                                                                            |
| Charge port                                       | USB Type-C connector to charge internal battery of the device                                                                                                                        | Micro USB connector for model STEMO300, and USB Type-C connector for model STEMO700 to charge internal battery of the device                                 | Similar                                                                                                         |
| Ambient noise cancelling                          | Model STEMO310 does not have ambient noise cancelling feature. STEMO710, STEMO720 and STEMO730 have ambient noise cancelling feature that can be turned on/off in the companion app. | Model STEMO300 does not have ambient noise cancelling feature. STEMO700 has ambient noise cancelling feature that can be turned on/off in its companion app. | Same. Ambient noise cancelling is an optional feature that an electronic stethoscope can have.                  |
| On device heart rate display                      | Model STEMO730 has on device heart rate display. Model STEMO310, STEMO710 and STEMO720 do not have on device heart rate display.                                                     | Has no on device heart rate display.                                                                                                                         | Substantially Equivalent. Heart rate display is an optional feature that an electronic stethoscope can have     |
| Audio output on the USB Type-C port of the device | Earphones supporting USB Type-C audio adapter accessory mode can be used to output the sounds.                                                                                       | Has no such analog audio output on the device.                                                                                                               | Substantially Equivalent. On-device audio output is an optional feature that an electronic stethoscope can have |
| Biocompatibility                                  | The diaphragm and the diaphragm retention ring contact patients.                                                                                                                     | The diaphragm and the diaphragm retention ring contact patients.                                                                                             | Same. The current device uses the same diaphragm and diaphragm retention ring                                   |



|  |  |  |                                                                            |
|--|--|--|----------------------------------------------------------------------------|
|  |  |  | as the predicate device, both in terms of materials and structural design. |
|--|--|--|----------------------------------------------------------------------------|

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 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/USEMCSC C63.27-2021 and AAMI TIR69:2017/(R2020) for wireless co-existence.

### 5.6.2 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

### 5.6.3 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.