November 25, 2024

Heroic Faith International Ltd.
℅ Tyra Chiu
Regulatory Consultant
Intellrac. ltd
1F., No. 4, Aly. 10, Ln. 467, Sec. 2, Zhonghua Rd.
Zhongzheng Dist.
Taipei, 100
Taiwan

Re: K242971
Trade/Device Name: AccurSound Electronic Stethoscope (AS101)
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 20, 2024
Received: September 26, 2024

Dear Tyra Chiu:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert T. Kazmierski -S

for

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242971

Device Name

AccurSound Electronic Stethoscope (AS101)

Indications for Use *(Describe)*

The AS-101 is an electronic stethoscope intended for the detection and amplification of sounds associated with the heart, lungs, arteries, veins, and other internal organs. It can be used on any person undergoing a physical assessment. The device is intended to be operated only by healthcare professionals for diagnostic decision support in clinical settings.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"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."

510(k) Summary

1. Submission Details

Heroic Faith International Ltd.
18F., No. 460, Sec. 4, Xinyi Rd.,
Xinyi Dist., Taipei City, 110
Taiwan (R.O.C.)
Phone: +886-22659-0291
Contract: Yuan-Ren Cheng, VP & CIO

2. Date Prepared

August 26, 2024

3. Device

Trade name:	AccurSound Electronic Stethoscope AS-101
Common name:	Electronic Stethoscope
Classification name:	Electronic Stethoscope (21 CFR 870.1875)
Device Class:	Class II
Product Code:	DQD
Classification Panel:	Cardiovascular

4. Predicate Device

AccurSound Electronic Stethoscope AS-101 (K221805)

5. Device Description

This submission is for device "The AccurSound Electronic Stethoscope AS-101 ("AS-101")". This submission expands upon a previously 510(k)-cleared device(K221805) by introducing two new reusable sensors, whereas the original device only included disposable sensors..

The AccurSound Electronic Stethoscope AS-101 ("AS-101") in this submission is a device designed for healthcare professionals used in clinical settings. The AS-101 can detect and amplify the sounds of the heart, lungs, arteries, veins, and other internal organs.

The microphone-equipped sensor detects and amplifies the sounds from the patient's body. The auscultation sound is digitally processed and filtered, electronically amplified in the hub unit. The anti-noise function reduces ambient noise and echoes, then transferred to the earpiece.

The multi-channel design allows healthcare professionals to attach disposable sensors or reusable sensors onto patient's body, by switching modes from handheld single-channel recording to four-channel stationery and continuously auscultation based on different requirements of clinical applications or physical assessments.

The associated accessories include:

- Disposable sensor(s)
- Reusable sensors(s)
- Patient cable(s)
- Earphone
- Power adapter with power cord

6. Intended Use/ Indications for Use

The AS-101 is an electronic stethoscope intended for the detection and amplification of sounds associated with the heart, lungs, arteries, veins, and other internal organs. It can be used on any person undergoing a physical assessment. The device is intended to be operated only by healthcare professionals for diagnostic decision support in clinical settings.

7. Comparison of technological characteristics with the predicate device

The modified AS-101 is substantially equivalent to previously 510(k)-cleared device AccurSound Electronic Stethoscope AS-101 (K221805) in terms of indications for use, technological characteristics, and safety and effectiveness. The comparison between the subject and predicate devices is provided in the table below.

	Candidate device AccurSound® Electronic Stethoscope AS-101	**Predicate device K221805** AccurSound Electronic Stethoscope AS-101 (K221805)	**Identical/ Similar/ Different**
Product classification			
Regulatory number	870.1875	870.1875	Identical
Product code	DQD	DQD	Identical
Classification	Class II	Class II	Identical
Power source			
Power Source	AC-to-DC supply	AC-to-DC supply	Identical
Intended use			
Intended use	The AS-101 is an electronic stethoscope intended for pickup and amplification of sounds associated with the heart, lungs, arteries, veins, and other internal organs. It can be used on any patient undergoing physical examinations. It is intended to be operated by medically qualified personnel for diagnostic purposes	The AS-101 is an electronic stethoscope intended for pickup and amplification of sounds associated with the heart, lungs, arteries, veins, and other internal organs. It can be used on any patient undergoing physical examinations. It is intended to be operated by medically qualified personnel for diagnostic purposes in clinics or hospitals.	Identical

	in clinics or hospitals.		

Device characteristics			
Sterility	Not intended to be sterilized	Not intended to be sterilized	Identical
Dimension	Control Hub: 99.0 x 71.0 x 16.6 mm	Control Hub: 99.0 x 71.0 x 16.6 mm	Identical
	Patient Cable: 1450 mm	Patient Cable: 1450 mm	
	Foam Sensor (chest-piece) diameter:-19.0 x 34.0 x 8.0 mm	Foam Sensor (chest-piece) diameter: 19.0 x 34.0 x 8.0 mm	
	Durable Sensor: 190×38×12 mm Sturdy sensor: 190×38×12 mm	-	Different. Introduce two reusable sensors
Patient -contacting materials	**Foam Sensor**: polyethylene foam single coated medical tape **Durable Sensor: Aluminum** **Sturdy Sensor: stainless**	**Foam Sensor**: polyethylene foam single coated medical tape	Different. Introduce two reusable sensors

Technological characteristics			
Principle of operation	The Accursound® Electronic Stethoscope AS-101 pick up sounds, such as heart, lung, and other internal organs sound from a patient's body. After amplification and filtering, the sounds are sent to the user through a set of earpiece. The sensor patch is designed for use with adult, pediatric, and infant patients. The user interface for the stethoscope includes a 4-button keypad and five LED indicators. Five LED indicators include 4 channel indicators and a power indicator.Sound Processing is carried out with a microcontroller and delivered to audio output. Power is supplied by an external power source through a medical-grade AC-DC power adapter, which has an input requirement of 100-240V. The power indicator turns solid green when the power is on.	The Accursound® Electronic Stethoscope AS-101 pick up sounds, such as heart, lung, and other internal organs sound from a patient's body. After amplification and filtering, the sounds are sent to the user through a set of earpiece. The sensor patch is designed for use with adult, pediatric, and infant patients. The user interface for the stethoscope includes a 4-button keypad and five LED indicators. Five LED indicators include 4 channel indicators and a power indicator.Sound Processing is carried out with a microcontroller and delivered to audio output. Power is supplied by an external power source through a medical-grade AC-DC power adapter, which has an input requirement of 100-240V. The power indicator turns solid green when the power is on.	Identical

Functions and performance			
Audio	headphones		Identical
Chest-piece	Single use Foam sensors Reusable sensors	Single use Foam sensors	Different Introduce two reusable sensors
Sound processing	Microcontroller as the digital signal processor	Microcontroller as the digital signal processor	Identical
Display and button panel	A 4-button keypad and five LED indicators. Five LED indicators include 4 channel indicators and a power indicator.	A 4-button keypad and five LED indicators. Five LED indicators include 4 channel indicators and a power indicator.	Identical
Bluetooth	No	No	Identical
Sound frequency range	20-2000 Hz	20-2000 Hz	Identical
Volume control	Yes	Yes	Identical
Volume control level	1-9 level	1-9 level	Identical

8. Performance Testing

Summary discussion of clinical data:

This submission does **NOT** include animal or clinical performance testing.

Summary discussion of non-clinical data:

The following non-clinical tests were conducted to evaluate the safety and performance of the modified AS-101 and provide evidence to support the verification and validation of AS-101:

- Electrical Safety and EMC tests are in compliance with ANSI/AAMI ES60601-1:2005/(R)2012/A1:2012, C1:2009/(R)2012/A2:2010/(R)2012 and ANSI/AAMI/IEC 60601-1-2:2014
- Biocompatibility evaluation in compliance with ISO 10993-1 was performed.
- Software level of concern is moderate. Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- Risk management according to ISO 14971:2019.

- Human factor engineering is in compliance with IEC 62366-1: 2015.

- Other bench test:
  - Performance Test
  - Cleaning Robustness Test

9. Substantial Equivalence

The subject device is a modified device based on previous cleared device(K221805). The subject device has same indications for use, technology, operation principle and technical characteristics with the predicate device. Verification activities were performed on subject device and all tests were verified to meet the required acceptance criteria. The verification tests demonstrate that the differences in the device do not affect the intended use of the device or raise any unsolved issues. There are no significant differences between subject device and the predicate device(s). We conclude that subject device is substantially equivalent to predicate devices.

10. Conclusion

Based on the information provided in this premarket notification, Heroic Faith International Ltd. believes the proposed modified AccurSound Electronic Stethoscope AS-101 and its predicate device, AccurSound Electronic Stethoscope AS-101 (K221805) are substantially equivalent in their intended use, both devices share same design and technology characteristics.