March 23, 2023

Heroic Faith International Ltd.
Yuan-Ren Cheng
VP & CIO
18F., No. 460, Section 4, Xinyi Road, Xinyi District
Taipei City, 110
Taiwan

Re: K221805
Trade/Device Name: AccurSound Electronic Stethoscope AS-101
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: February 16, 2023
Received: February 21, 2023

Dear Yuan-Ren Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221805

Device Name
AccurSound Electronic Stethoscope AS-101

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.

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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

March 22, 2023

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

3M Littmann Electronic Stethoscope, Model 3200 (K083903)

5. Device Description

The AccurSound Electronic Stethoscope AS-101 (“AS-101”) 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 disposable 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 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)
- 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 AS-101 is substantially equivalent to the predicate device 3M Littmann Electronic Stethoscope Model 3200 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 K083903** 3M™ Littmann® Electronic Stethoscope Model 3200	**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	AA alkaline, lithium, or NiMH battery	Different
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 in clinics or hospitals.	3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selective frequency ranges. It can be used on any patients undergoing a physical assessment.	Identical

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	Total length: 690 mm	Different
	Patient Cable: 1450 mm	N/A	
	Sensor (chest-piece) diameter: 19.0 x 34.0 x 8.0 mm	Diaphragm diameter: 51 mm	
Patient -contacting materials	**Sensor**: polyethylene foam single coated medical tape	**Chest-piece**: metal	Different
Single-use	Foam sensor is single-use	Reusable chest-piece and the diaphragm can be removed for cleaning	Different

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 disposable 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 3M™ Littman® Electronic Stethoscope Model 3200 picks up sounds, such as heart and lung sounds, from a patient's body. After amplification and filtering, the sounds are sent to the user through a binaural headset. The stethoscope chestpiece is designed for use with adult, pediatric, and infant patients. The user interface for the stethoscope includes a 5-button keypad and an LCD display. Sound processing is carried out with the aid of a digital signal processor. Stethoscope power is provided by a single AA battery in the chestpiece. A power management system is included to prolong battery life. Using its Bluetooth wireless link, the stethoscope can exchange audio data with an external device such as a personal computer (PC).	Similar

Functions and performance			
Audio	headphones	Binaural headset	Different
Chest-piece	Foam sensors	Metallic chest-piece	Different
Sound processing	Microcontroller as the digital signal processor	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.	LCD 5-button keypad	Different
Bluetooth	No	Yes	Different
Sound frequency range	20-2000 Hz	Bell mode: 20-200 Hz Diaphragm mode: 100-500 Hz Extended range: 50-500 Hz	Similar
Volume control	Yes	Yes	Identical
Volume control level	1-9 level	1-9 levels	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 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:
  - LED Indicator Behavior Test Report
  - Button Selector Test Report
  - Hardware Sound Band Pass Filter Test Report
  - Total Harmonic Distortion and Noise Test Report
  - Acoustic Frequency Response Test Report
  - Sample Rate Test Report
  - Overall Sound Amplification Ratio Test Report
  - Multiple Channels Test Report
  - I2C Communication Test Report
  - Audio Comparison of the Foam Sensors Test Report
  - Data Transmission Test Report
  - Test for Degrees of Protection Provided by Enclosures Test Report

9. Substantial Equivalence

The subject device has same indications for use, technology, and operation principle as well as similar 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 AccurSound Electronic Stethoscope AS-101 and its predicate device, the 3M Littmann Model 3200 Electronic Stethoscope are substantially equivalent in their intended use, both devices share similar design and technology characteristics.