March 29, 2023

Sparrow Acoustics Inc.
Nadezda Ivanova
Chief Product Officer
2416 Natura Drive
Lucasville, NS B4B 0X3
Canada

Re: K222871
Trade/Device Name: Stethophone v1
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: September 21, 2022
Received: September 22, 2022

Dear Nadezda Ivanova:

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)*
K222871

Device Name

Stethophone v1

Indications for Use *(Describe)*

Stethophone v1 is intended for medical diagnostic purposes only. It may be used for detection and amplification of sounds from the heart and lungs with the use of selective frequency ranges. It can be used on adults undergoing physical assessment.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

1.	Summary Date:	September 21, 2022
2.	Submitter:	Sparrow Acoustics Inc. 2416 Natura Dr. Lucasville, NS Canada, B4B 0X3 Tel: +1 (902) 989-3908
3.	Correspondent:	Nadia Ivanova
4.	Device Trade Name:	Stethophone v1
5.	Device Common Name:	Smartphone stethoscope
6.	Classification:	Electronic Stethoscope 21 CFR 870.1875(b) Class II Product Code: DQD Panel: Cardiovascular
7.	Intended Use/ Indications for Use:	Stethophone v1 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart and lungs with the use of selective frequency ranges. It can be used on adults undergoing physical assessment.

8.	Device Description:	Stethophone v1 is an electronic stethoscope software application that operates on smartphones.
		Stethophone v1 allows for the capture and amplification of chest sounds that are listened in real-time or recorded, cloud storage of sound records, sound filtering for selected frequency ranges, and visualization to assist in sound analysis.
		Stethophone v1 is designed to assist healthcare providers to hear and visualize heart and lung sounds during a physical examination of a patient as well as storing recorded sounds for later analysis.
		Stethophone v1 is a decision support device used for the assessment of chest sounds of adult patients in clinical and non-clinical environments.
		Key product features:
		• Acquiring sound through the smartphone microphone
		• Real-time listening of chest sounds
		• Recording of chest sounds
		• Two modes of sound visualization: oscillogram and spectrogram
		• Selecting among three sound filters for listening:
		  ○ Bell: Classic filter used for low frequency sounds
		  ○ Diaphragm: Classic filter used for higher frequency sounds of heart and lungs
		  ○ Starling: Filter for listening to the full frequency of chest sounds

9. Predicate Devices:

Steth IO® Smartphone Stethoscope and Phonocardiogram, Model 1.0	**3M™ Littmann® Electronic Stethoscope, Model 3200**
510(k) Number: K160016 Manufacturer: StratoScientific, Inc. Product Code: DQD Classification: 870.1875(b)	510(k) Number: K083903 Manufacturer: 3M Company Product Code: DQD Classification: 870.1875(b)

10. Comparison to Predicates: The comparison chart below provides evidence to facilitate the substantial equivalence determination between Stethophone v1 to the predicate devices with respect to intended use, technological characteristics, and principles of operation.

	Stethophone v1	**Steth IO® (primary)**	**3M™ Littmann® Model 3200**	**Comments**
Classification				
Classification	Class II device	Class II device	Class II device	Same
Regulation	21 CFR 870.1875(b)	21 CFR 870.1875(b)	21 CFR 870.1875(b)	Same
Product code	DQD	DQD	DQD	Same
Device	Stethoscope, Electronic	Stethoscope, Electronic	Stethoscope, Electronic	Same
FDA Clearance	Pending	k160016	K083903	
Intended Use/Indications for Use				
Intended Use/ Indications for Use	Stethophone v1 is intended for medical diagnostic purposes only. It may be used for detection and amplification of sounds from the heart and lungs with the use of selective frequency ranges. It can be used on adults undergoing physical assessment.	The StratoScientific Steth IO Stethoscope and Phonocardiogram Model 1.0 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, and lungs with the use of selective frequency ranges. It has been tested for use on adults undergoing a physical assessment.	The 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 a selective frequency. It can be used on any person undergoing a physical assessment.	Substantially equivalent
Prescription/ OTS	Prescription	Prescription	Prescription	Same
Population Type	Adults	Adults	All types of patients	Same with Steth IO, narrower population than Littmann 3200,

				which doesn't affect safety and performance for the proposed intended use
Principles of Operation				
Form Factor	Device that is held in the Doctor's hand is the form of the smartphone	Device that is held in the Doctor's hand is the form of the smartphone	Similar to a traditional stethoscope	Same as Steth IO. Different than Littmann 3200, which doesn't affect safety and performance
Dedicated Device vs. iPhone	Operates on iPhone smartphone using its hardware and operating system	Operates on iPhone smartphone using its hardware and operating system	Dedicated proprietary hardware (chest piece)	Same as Steth IO. Different than Littmann 3200, which doesn't affect safety and performance
iPhone model Compatibility	6s, 6S Plus, SE 1st gen, 7, 7 Plus, 8, 8 Plus, X, XS, XS MAX, XR, SE 2 generation, 11, 11 Pro, 11 Pro Max, 12, 12 Pro, 12 Mini, 12 Pro Max, 13 mini, 13, 13 Pro, 13 Pro Max	iPhone 6, 7/8, 7+ or 8+, X	N/A	Stethophone v1 is available for a larger number of iPhone models than Steth IO, which may affect availability, but doesn't affect safety and performance as stethoscopes
Software Platform	iOS	iOS	Windows, MacOS	Same as Steth IO. Different than Littmann 3200, which may affect availability, but doesn't affect safety and performance as stethoscopes
Sound Type	Heart, lungs	Heart, lungs	Heart, lungs, arteries, veins, and other internal organs	Same with Steth IO, narrower than Littmann 3200, which doesn't affect safety and performance for the proposed intended use
Signal Input Method	Uses microphone of the smartphone to acquire a sound	Uses microphone of the smartphone to acquire a sound	Uses microphone of the stethoscope to acquire a sound	Same as Steth IO, equivalent to Littmann 3200
Audio Output Method	Headphones	Headphones	Eartubes with eartips	Same as Steth IO, equivalent to Littmann 3200

Record and Playback Sounds	Yes	Yes	Yes	Same
Real-Time Auscultation	Yes	Yes	Yes	Same
Filter Selection	Yes	Yes	Yes	Same
Digital Signal Processing (DSP)	Yes	Yes	Yes	Same
Display	Smartphone screen	Smartphone screen	LCD display of the device	Same as Steth IO, equivalent to Littmann 3200
Sound Visualization	Yes	Yes	Yes	Same
Technical Characteristics				
Frequency Response	Stethophone v1 picks up and amplifies the sound between 20 and 2000 Hz. Based on the selected audio filter, specific frequency ranges are further emphasized: Bell filter emphasizes range from 25 to 300 Hz Diaphragm filter emphasizes frequency spectrum range 170-850 Hz, Starling filter works between 60 -1400 Hz	Steth IO has two filters: Heart and Lung. The specific frequency filtration of these filters corresponds to Stethophone's Bell (high-cut filter) and closely to Stethophone's Diaphragm and Starling filters. This correspondence is based on frequency response curves.	The Bell mode amplifies sounds from 20 – 1000 HZ, but emphasizes lower frequency sounds between 20 - 200Hz. The Diaphragm mode amplifies sounds from 20 – 2000 Hz but emphasizes the sounds between 100 – 500 Hz. The Extended Range mode amplifies sounds from 20 - 2000Hz similar to the Diaphragm Mode but provides more Low-frequency response between 50 - 500Hz.	Substantially equivalent
Volume Control	Yes	Yes	Yes	Same
Battery	Uses a built-in battery of a smartphone	Uses a built-in battery of a smartphone	Uses a built-in battery of a chestpiece	Same as Steth IO, equivalent to Littmann 3200
Recording Lengths	20 sec	Up to 1 min	Maximum of 29 seconds for on-board recording, up to 1 min for wireless recording to computer software	Substantially Equivalent, differences don't affect safety and effectiveness
Available Sound Visualization	Spectrogram, oscillogram	Spectrogram, oscillogram	Spectrogram, oscillogram	Same
Ability to Zoom Visualization	Yes	Yes	Yes	Same

The proposed device Stethophone v1 and the predicate devices Steth IO and Littmann 3200 share the same intended use, design, user functions and fundamental scientific operational technology. The devices are functionally the same: all three devices capture, amplify the sound, use frequency filters, visualize via two types of graphs (oscillogram and spectrogram), store records and allow auscultating heart and lung sound in real time. Software comparison and their validation support the equivalency claim. Performance and usability comparison testing was performed to support the equivalence claims.

11.	Performance Data:	Sparrow Acoustics Inc. submitted performance testing information in this 510(k) to demonstrate safety and efficacy of Stethophone v1, to validate that the device meets predetermined specifications and performs according to pre-specified acceptance criteria, and to support the substantial equivalence determination. Testing includes repeatability and reproducibility tests, performance tests using an anechoic chamber, internal tests run by a medical analysts' team, tests involving external medical specialists with auscultation experience, as well as a usability and performance study conducted by an independent medical facility.
12.	Biocompatibility Testing:	Not Applicable (Standalone Software)
13.	Sterilization & Shelf-life Testing:	Not Applicable (Standalone Software). Therefore, it is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.
14.	Electrical safety and electromagnetic compatibility (EMC):	Not Applicable (Standalone Software). Therefore, there is no source of risk for electrical safety or electromagnetic compatibility associated directly with the device.
15.	Animal Study:	Animal performance testing was not required to demonstrate safety and effectiveness of the device.
16.	Human Clinical Performance Testing:	Clinical testing was not required to demonstrate the safety and effectiveness of the device.
17.	Statement of Substantial Equivalence:	Stethophone v1 and the predicate devices Steth IO and Littmann 3200 share the same intended use, design, user functions and fundamental scientific operational technology. The devices are functionally the same. Software comparison and their validation support the equivalency claim. The differences that exist between the devices do not affect the relative safety and/or effectiveness. Sparrow Acoustics believes the Stethophone v1 device and its predicates Steth IO (Model 1.0) and 3M Littmann Electronic Stethoscope, Model 3200 used in conjunction with the Littmann StethAssist phonocardiogram software, are substantially equivalent.

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.