October 12, 2023

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

Re: K231551
Trade/Device Name: Stethophone
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 29, 2023
Received: May 30, 2023

Dear Nadia 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.

Submission Number *(if known)*

K231551

Device Name

Stethophone

Indications for Use *(Describe)*

Stethophone is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs), whereby a clinician at one location can listen to the auscultation sounds of a patient acquired on site or at a different location. Stethophone is intended for use on adult patients. Stethophone is intended to be used by professional or lay users in a clinical or nonclinical environment. Stethophone is not intended for self-diagnosis.

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.

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."

K231551 - 510(k) SUMMARY

1.	Summary Date:	May 31, 2023
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
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 is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs), whereby a clinician at one location can listen to the auscultation sounds of a patient acquired on site or at a different location. Stethophone is intended for use on adult patients. Stethophone is intended to be used by professional or lay users in a clinical or nonclinical environment. Stethophone is not intended for self-diagnosis.
8.	Device Description:	Stethophone is an electronic stethoscope software application that operates on smartphones. Stethophone is designed for use by both healthcare professionals and home users. Stethophone enables the capture and amplification of chest sounds for real-time or recorded listening. Cloud storage with sound record sending capabilities, filtering for selected frequency ranges, and visualization all assist with sound analysis. Stethophone is designed to assist healthcare providers both in hearing and visualizing heart and lung sounds during a physical examination of a patient and in storing recorded sounds in cloud for later analysis. It also enables home users to record and send chest sounds to their physicians. Stethophone is a decision support device used for the assessment of chest sounds of adult patients in clinical and non-clinical environments. Assessment is performed by healthcare providers, while sound capturing can be performed by both healthcare providers and home users.

Key product features:

- Capturing chest sounds using the smartphone microphone:
  - Real-time listening to chest sounds,
  - Recording of chest sounds,
- Sending examinations to specialists for assessment
- Two modes of sound visualization: oscillogram and spectrogram, and
- Selection of three audio filters for listening:
  - Bell: Traditional filter used for low frequency sounds,
  - Diaphragm: Traditional filter used for higher frequency sounds of heart and lungs, and
  - Starling: Filter for listening to the full frequency of chest sounds.

Collectively, these features enable a healthcare professional to examine and monitor patients, seek out second opinions from specialists, and use the device in a telemedicine context.

9. Predicate Devices:

Stethophone v1

510(k) Number: K222871
Manufacturer: Sparrow Acoustics Inc.
Product Code: DQD
Classification: 870.1875

Eko CORE

510(k) Number: K200776
Manufacturer: Eko Devices, Inc.
Product Code: DQD
Classification: 870.1875

10. Comparison to Predicates:

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

	Stethophone	**Stethophone v1 (primary)**	**Eko CORE**	**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	K222871	K200776	
Intended Use/Indications for Use				
Intended Use/Indications for Use	Stethophone is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs), whereby a clinician at one location can listen to the auscultation	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	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	Substantially Equivalent

	sounds of a patient acquired on site or at a different location. Stethophone is intended for use on adult patients. Stethophone is intended to be used by professional or lay users in a clinical or nonclinical environment. Stethophone is not intended for self-diagnosis.	undergoing physical assessment.	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 pediatric and adult patients. The Eko CORE 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/OTS	Prescription and OTC	Prescription	Prescription and OTC	Same
Population Type	Adults	Adults	Pediatric and adults	Same with Stethophone v1, narrower population than Eko CORE, 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	Attachment to an analog stethoscope	Same as Stethophone v1. Different than Eko CORE, 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 (Attachment to an analog stethoscope)	Same as Stethophone v1. Different than Eko CORE, which doesn't affect safety and performance
iPhone model Compatibility	6s, 6S Plus, SE 1st generation, 7, 7 Plus, 8, 8 Plus, X,	6s, 6S Plus, SE 1st gen, 7, 7 Plus, 8, 8 Plus, X, XS, XS	Any model	Stethophone is available for a larger number

	XS, XS MAX, XR, SE 2nd generation, 11, 11 Pro, 11 Pro Max, 12, 12 Pro, 12 Mini, 12 Pro Max, 13 mini, 13, 13 Pro, 13 Pro Max, SE 3rd generation, 14, 14 Pro, 14 Pro Max	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		of iPhone models than Stethophone v1, which may affect availability, but doesn't affect safety and performance as stethoscopes
Software Platform	iOS	iOS	iOS, Android	Same as Stethophone v1. narrower than Eko CORE, which may affect availability, but doesn't affect safety and performance as stethoscopes
Sound Type	Heart, lungs	Heart, lungs	Heart, lungs, bowel, arteries, and veins	Same as Stethophone v1. narrower than Eko CORE, which may affect availability, but 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 attached analog stethoscope to acquire sound and smartphone to record sound	Same as Stethophone v1. Different than Eko CORE, which doesn't affect safety and performance
Audio Output Method	Headphones	Headphones	Eartubes of the attached analog stethoscope. Bluetooth headphones paired with Eko App installed on a smartphone can also be used	Same as Stethophone v1, equivalent to Eko CORE

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	Smartphone screen via Eko App	Same
Sound Visualization	Yes	Yes	Yes	Same
Technical Characteristics				
Frequency Response	Stethophone 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.	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.	The default filter is Wide but Cardiac and Pulmonary filters can also be selected to allow the lower and higher frequencies to be emphasized in the sound profile, respectively	Same with Stethophone v1; substantially equivalent to Eko CORE
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	Same with Stethophone v1; substantially equivalent to Eko CORE
Recording Lengths	20 sec	20 sec	15-120 sec	Same with Stethophone v1; substantially equivalent to Eko CORE
Available Sound Visualization	Spectrogram, oscillogram	Spectrogram, oscillogram	Oscillogram	Same with Stethophone v1; substantially equivalent to Eko CORE
Ability to Zoom Visualization	Yes	Yes	Yes	Same

11.	Performance Data:	Sparrow Acoustics Inc. submitted performance testing information in this 510(k) to demonstrate safety and efficacy of Stethophone, 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 lay users and external medical specialists with auscultation experience.
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.	Clinical Performance Testing:	Clinical testing was not required to demonstrate the safety and effectiveness of the device.
17.	Statement of Substantial Equivalence:	Stethophone and the predicates have the same intended use and similar indications, technological characteristics, and principles of operation. The minor differences do not present different questions of safety or effectiveness than the predicate device. Performance data demonstrates that Stethophone is as safe and effective as the predicate devices. Thus, Stethophone is substantially equivalent to the predicate devices.

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