September 19, 2024

Sparrow Acoustics Inc.
Nadia Ivanova
Chief Product Officer
2416 Natura Dr
Lucasville, NS B4B0X3
Canada

Re: K240901
Trade/Device Name: Stethophone Pro
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: April 1, 2024
Received: April 2, 2024

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 (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
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: 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.

510(k) Number *(if known)*
K240901

Device Name

Stethophone Pro

Indications for Use *(Describe)*

Stethophone Pro is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs).

Stethophone Pro is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms and can automatically detect murmurs that may be present, sound timing and character, including S1, S2, and the absence of a heart murmur.

Stethophone Pro is not intended to be used as a sole means of diagnosis and is for use in environments where health care is provided by clinicians. The interpretations of heart sounds offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. The interpretations are not diagnoses. Stethophone Pro is intended for use on adult patients.

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 18, 2024
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 Pro
5.	Device Common Name:	Smartphone stethoscope
6.	Classification:	Electronic Stethoscope 21 CFR 870.1875(b) Class II Product Code: DQD, DQC Panel: Cardiovascular
7.	Intended Use/ Indications for Use:	Stethophone Pro is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs). Stethophone Pro is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms and can automatically detect murmurs that may be present, sound timing and character, including S1, S2, and the absence of a heart murmur. Stethophone Pro is not intended to be used as a sole means of diagnosis and is for use in environments where health care is provided by clinicians. The interpretations of heart sounds offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. The interpretations are not diagnoses. Stethophone Pro is intended for use on adult patients.
8.	Device Description:	Stethophone Pro is an electronic stethoscope software application that operates on smartphones. Stethophone Pro is designed for use by healthcare professionals or on the order of healthcare professionals. Stethophone Pro 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 Pro is designed to assist healthcare professionals in both hearing and visualizing heart and lung sounds during a physical examination of a patient and in storing recorded sounds in the cloud for

later analysis. It also enables home users to record and send chest sounds to their physicians.

Stethophone Pro can be used for the assessment of chest sounds of adult patients in clinical and non-clinical environments. Assessment is performed by healthcare professionals, while sound capturing can be performed by both healthcare professionals and home users.

Stethophone Pro performs basic analysis of heart sounds allowing to detect the presence of murmurs, locate heartbeats on the timeline (S1/S2), and calculate timing between them.

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,
- Detecting murmurs, timing for S1 and S2 sounds, and calculating heart rate,
- Selecting from three audio filters for listening:
  - Bell: Traditional filter used in stethoscopes 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 users to acquire heart sounds and receive basic reporting, so as enable healthcare professionals to examine and monitor patients on site and remotely, seek out second opinions from specialists, and use the device in a telemedicine context.

9. Predicate Devices:

Stethophone	**Eko Murmur Analysis Software**
510(k) Number: K231551 Manufacturer: Sparrow Acoustics Inc. Product Code: DQD Classification: 870.1875	510(k) Number: K213794 Manufacturer: Eko Devices, Inc. Product Code: DQD, DQC, DPS Classification: 870.1875

10. Comparison to Predicates:

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

	Stethophone Pro	**Stethophone (primary)**	**Eko Murmur Analysis Software**
Classification	Class II device	Class II device	Class II device
US FDA Regulation	21 CFR 870.1875(b)	21 CFR 870.1875(b)	21 CFR 870.1875(b)
Product code	DQD, DQC	DQD	DQD, DQC, DPS
Device	Stethoscope, Electronic	Stethoscope, Electronic	Stethoscope, Electronic

US FDA 501k Number	K240901	K231551	K213794
Intended Use/Indications for Use	Stethophone Pro is an electronic stethoscope that enables detection, amplification, filtering, and transmission of auscultation sound data (heart and lungs). Stethophone Pro is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms and can automatically detect murmurs that may be present, sound timing and character, including S1, S2, and the absence of a heart murmur. Stethophone Pro is not intended to be used as a sole means of diagnosis and is for use in environments where health care is provided by clinicians. The interpretations of heart sounds offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. The interpretations are not diagnoses. Stethophone Pro is intended for use on adult patients.	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.	The Eko Murmur Analysis Software is intended to provide decision support to clinicians in their evaluation of patients' heart sounds. The software analyzes heart sounds and phonocardiograms (and ECG signals, when available). The software will automatically detect murmurs that may be present, and the murmur timing and character, including S1, S2, innocent heart murmurs, structural heart murmurs, and the absence of a heart murmur. The Eko Murmur Analysis Software is not intended as a sole means of diagnosis and is for use in environments where health care is provided by clinicians. The interpretations of heart sounds offered by the software are meant only to provide decision support to the clinician, who may use the result in conjunction with their own evaluation and clinical judgment. The interpretations are not diagnoses. The Eko Murmur Analysis Software is intended for use on pediatric and adult patients.
Prescription/ OTC	Prescription	Prescription and OTC	Prescription
Population Type	Adults	Adults	Pediatric and adults
Device Type	Standalone software for smartphone	Standalone software for smartphone	Standalone software for further integration via API
Dedicated Device vs. Smartphone	Operates on smartphone using its hardware and operating system	Operates on smartphone using its hardware and operating system	Operates on smartphone using its hardware and operating system, when used as part of Eko App

iPhone model Compatibility	6s, 6S Plus, SE 1st generation, 7, 7 Plus, 8, 8 Plus, X, 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 Plus, 14 Pro, 14 Pro Max, 15, 15 Plus, 15 Pro, 15 Pro Max	6s, 6S Plus, SE 1st generation, 7, 7 Plus, 8, 8 Plus, X, 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 Plus, 14 Pro, 14 Pro Max, 15, 15 Plus, 15 Pro, 15 Pro Max	No dependency on the smartphone model is noted when used as part of Eko App
Software Platform	iOS	iOS	Available for iOS or Android when used as part of Eko App
Sound Type	Heart, lungs	Heart, lungs	Heart
Signal Input for Processing	Processes chest sound and analyzes heart sounds and phonocardiograms	Processes chest sound	Processes heart sound and analyzes heart sounds and phonocardiograms
Sound Processing	Yes	Yes	Yes
Ability to Visualize Sound	Spectrogram, oscillogram	Spectrogram, oscillogram	Oscillogram
Murmur detection	Yes	N/A	Yes
Heart sound timing	Yes	N/A	Yes
Signal quality assessment	Yes	N/A	Yes

11. Performance Data:

Sparrow Acoustics Inc. submitted performance testing information in this 510(k) to demonstrate safety and efficacy of Stethophone Pro, 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 and performance tests for acoustics as well as performance tests for heart sound analysis.

For validation of its proprietary algorithms for heart sound analysis, Stethophone Pro underwent a thorough testing process to ensure its safety, reliability and effectiveness. Testing included both software verification and validation, as well as clinical validation.

Stethophone Pro algorithms for heart sound analysis have been validated in both retrospective and clinical performance testing on a combination of proprietary and public clinical data. Validation was performed after the algorithm development and training was finalized.

The retrospective testing data consisted of 7,304 heart sound recordings made on 2,277 adult subjects. Of these, 4,396 recordings belonged to a proprietary dataset and were recorded using a variety of devices including smartphones as well as commercially available stethoscopes. Out of those, 45.2% were females and 54.8% were males. The age of subjects ranged from 18 to 91 years old. Ethnicity is represented by 86.1% white, 6.1% as Latino, 5.0% as Asian, and 2.7% as African American.

Each recording in a testing dataset was annotated by multiple expert cardiologists. Annotation of each recording included determining the presence of a heart murmur of any type and providing timings of all S1 and S2 heart sounds that were audible in the recording. Heart murmurs were observed in 54.2% of recordings.

There was no overlap between subjects and recordings included in the testing and training data.

The following tables demonstrate the results of device performance for the primary indicators:

Heart sound timing

Metric	Dataset	Test result
S1 precision	America	97.1 95% CI: (96.7 to 97.5)
	Multi-Device	96.9 95% CI: (96.6 to 97.3)
S1 sensitivity (recall)	America	97.3 95% CI: (97.0 to 97.7)
	Multi-Device	97.9 95% CI: (97.7 to 98.1)
S2 precision	America	97.5 95% CI: (97.2 to 97.9)
	Multi-Device	97.1 95% CI: (96.7 to 97.4)
S2 sensitivity (recall)	America	96.5 95% CI: (96.1 to 97.0)
	Multi-Device	97.7 95% CI: (97.5 to 97.9)

Murmur detection

Metric	Dataset	Test result
Sensitivity	America	88.7 95% CI: (87.2 to 89.8)
	Multi-Device	93.0 95% CI: (91.9 to 94.2)
Specificity	America	89.2 95% CI: (87.2 to 91.3)
	Multi-Device	94.4 95% CI: (93.7 to 95.4)
Accuracy	America	88.8 95% CI: (87.6 to 89.8)
	Multi-Device	93.8 95% CI: (93.2 to 94.6)
ROC AUC	America	96.9 95% CI: (96.1 to 97.3)
	Multi-Device	97.9 95% CI: (97.5 to 98.3)

Heart rate

Metric	Dataset	Test result
MAE	America	0.482 bpm 95% CI: (0.418 to 0.557)
	Multi-Device	0.389 bpm 95% CI: (0.346 to 0.430)

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 trial was not required to demonstrate the safety and effectiveness of the device. Bench testing mentioned in the Performance section was done using clinically collected data.
17.	Statement of Substantial Equivalence:	Stethophone Pro and the predicates have the same intended use and similar indications, technological characteristics, and principles of operation, and were assessed on similar performance metrics with the comparable results. The minor differences do not present different questions of safety or effectiveness than the predicate device. Extensive performance testing was conducted for both acoustics and heart sound analysis algorithms. Performance data demonstrates that Stethophone Pro is as safe and effective as the predicate devices. Thus, Stethophone Pro is substantially equivalent to the predicate devices. The minor differences in indications do not introduce a new intended use and do not raise different questions of safety and effectiveness.

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