April 27, 2022

Strados Labs, Inc.
% Prithul Bom
Most Resonsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220893
Trade/Device Name: Strados Remote Electronic Stethoscope Platform (RESP)
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH
Dated: March 25, 2022
Received: March 28, 2022

Dear Prithul Bom:

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,

For Brandon Blakely, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K220893

Device Name
Strados Remote Electronic Stethoscope Platform (RESP)

Indications for Use *(Describe)*
The Strados Remote Electronic Stethoscope Platform (RESP) is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record, and store lung sounds from adult patients in a healthcare or outpatient setting including transition from healthcare setting to outpatient care without interruption. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.

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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Section 5
510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Strados RESP Traditional 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
Strados Labs, Inc.
1315 Walnut Street, Suite 1101
Philadelphia, PA 19107
Tel: (888) STRADOS

Submission Contact:
Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
grace@powersregulatory.com

Submission Date:
March 1, 2022

Subject Device:
Trade Name: Strados Remote Electronic Stethoscope Platform (RESP)
Common Name: Medical magnetic tape recorder
Classification Name: Recorder, Magnetic Tape, Medical
Regulation: 21 CFR §870.2800
Regulatory Classification: Class 2
Product Code**:** DSH

Predicate Device:
Trade Name: Strados Remote Electronic Stethoscope Platform (RESP)
Common Name: Medical magnetic tape recorder
Classification Name: Recorder, Magnetic Tape, Medical
Regulation: 21 CFR §870.2800
Regulatory Classification: Class 2
Product Code**:** DSH
510(k): K201077

Device Description

The Strados Remote Electronic Stethoscope Platform (RESP) is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record, and store lung sounds from adult patients. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient. The Strados Remote Electronic Stethoscope Platform (RESP) is comprised of the Strados Wearable Device (SWD), Strados Charging Station (SCS) and external power supply, and Strados Patient Adhesive (SPA) used to adhere the SWD to the patient. The SWD is controlled by a mobile device running the Strados Mobile Application (SMA) via Bluetooth connection. The Strados Wearable Device (SWD) sits on the chest wall and passively records the patient's airway sounds, including but not limited to cough, wheeze, rhonchi, rales, crackles, coarse (bronchial) breath sounds, quiet breathing, and chest wall movement onto internal memory. The Strados Mobile App (SMA) on a smartphone allows playback of lung sounds from the wearable device in order for clinicians to listen to the patient's lung sounds. The device is used in a healthcare and outpatient setting including the home.

Table 5-1: Strados Labs, Inc. Strados Remote Electronic Stethoscope Platform (RESP) Product Offerings

Product Offering	Catalog Number	Contents
Strados Remote Electronic Stethoscope Platform (RESP)	RESP1	One system contains: • Two (2) Strados Wearable Device • Adhesives • Charging Station with wall adaptor • Labeling
Strados Wearable Device	SWD1	Sold individually
Strados Patient Adhesives	SPA1	Sold in a pack
Strados Charging Station	SCS1	Sold individually. Contains Charging Station and wall adapter
Strados Mobile Application	540-00001	Downloaded on a mobile device

Intended Use/Indications for Use

The Strados Remote Electronic Stethoscope Platform (RESP) is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record, and store lung sounds from adult patients in a healthcare or outpatient setting including transition from healthcare setting to outpatient care without interruption. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.

Technological Characteristics

An overview comparison of the Strados Remote Electronic Stethoscope Platform (RESP) (subject device) to the predicate device is presented in the table below.

Table 5-2: Device Comparison

	Subject Device: Strados RESP	**Predicate Device: Strados RESP K201077**
Name	Strados Remote Electronic Stethoscope Platform (RESP)	Strados Remote Electronic Stethoscope Platform (RESP)
Manufacturer	Strados Labs, Inc.	Strados Labs, Inc.
Product Code	DSH	DSH
Regulation Number	21 CFR 870.2800	21 CFR 870.2800
Device Classification Name	Recorder, Magnetic Tape, Medical	Recorder, Magnetic Tape, Medical
Device Classification	Class 2	Class 2
Indication for Use	The Strados Remote Electronic Stethoscope Platform (RESP) is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record, and store lung sounds from adult patients in a healthcare or outpatient setting including transition from healthcare setting to outpatient care without interruption. The device stores the data for later playback, review, and analysis by a clinician and comparison with earlier data from the same patient.	The RESP is a non-invasive battery-operated device, including a wearable component, intended to longitudinally acquire, record, and store lung sounds from adult patients in a healthcare setting. The device stores the data for later playback, review, and analysis by a clinician on a mobile app.
Age of Device Use	Adults.	Adults.
Principle of Operation	**Placement**- The Strados RESP is adhered in an area of interest by a clinician to the skin (Healthcare setting). Device placement is determined by the clinician. The patient places and replaces the device on themselves (Outpatient setting). **Recording**- Lung sounds are recorded by wearable and stored in internal storage. A clinician configures the options. **Transmission**- Recordings are transmitted to the Strados Mobile App (SMA) from internal storage on the SWD. **Playback**- Recordings can be played back via the SMA or Clinical Portal.	**Placement**- The Strados RESP is adhered in an area of interest by a clinician to the skin. **Recording**- Lung sounds are recorded by wearable and stored in internal storage. A clinician configures the options. **Transmission**- Recordings are transmitted to the Strados Mobile App (SMA) from internal storage on the SWD. **Playback**- Recordings can be played back via the SMA or Clinical Portal.
Condition of Use	Reusable	Reusable
Rx or OTC	Prescription Only	Prescription Only
Wearable	Yes	Yes

Non-Clinical Performance Data

The subject device was subject to non-clinical performance testing. There are no device-specific guidance documents, special controls document, and/or requirements in a device-specific regulation that is applicable to the subject device. A list of the standards, guidance and additional testing for all the devices is listed below:

- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- AAMI/IEC 60601-1:2005 + AMD 1:2012- Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015- Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366-1:2015- Medical devices — Part 1: Application of usability engineering to medical devices
- IEC 62304:2006-Medical device software — Software life cycle processes
- UL 62368-1:2012- Audio/video, information and communication technology equipment - Part 1: Safety requirements

  IEC 60601-1-6:2010- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- Additional Non-Clinical performance testing conducted for this submission includes:
  - Frequency response equivalence testing
  - Device Cleaning Testing
  - Usability Testing

Clinical Performance Data

Clinical performance testing was performed to validate the quality and fidelity of the subject device's recorded lung sounds when self-placed and recorded in an outpatient setting.

Conclusion

The Strados Remote Electronic Stethoscope Platform (RESP) is substantially equivalent to the legally marketed predicate device as demonstrated by the similar indication for use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.