December 20, 2020

Strados Labs
% Grace Powers
Principal Consultant
Powers Regulatory Consulting|64954
2451 Cumberland Parkway SE Suite 3740
Atlanta, Georgia 30339

Re: K201077
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: November 23, 2020
Received: November 24, 2020

Dear Grace Powers:

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,

James J. Lee, Ph.D.
Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201077

Device Name
Strados Remote Electronic Stethoscope Platform (RESP)

Indications for Use *(Describe)*
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.

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

Submission Date: April 21, 2020

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: Vitalograph Model 7100 VitaloJAK (K110525)
Reference Device: 3M™ Littmann® Electronic Stethoscope Model 3200 (K083903)

Device Description
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.
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 lung sounds. 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 setting.

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 • Pack of 100 adhesives • Charging Station with wall adaptor • IFU
Strados Wearable Device	SWD1	Sold individually
Strados Patient Adhesives	SPA1	Sold as a pack of 100
Strados Charging Station	SCS1	Sold individually. Contains Charging Station and wall adapter
Strados Mobile Application	540-00001	Downloaded on a mobile device (mobile device not provided)

Intended Use/Indications for Use

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.

Technological Characteristics

The Strados Remote Electronic Stethoscope Platform (RESP) has similar technological characteristics as the predicate device, Vitalograph Model 7100 VitaloJAK via K110525. A comparison table including the reference device is provided below.

Table 5-2: Device Comparison

	Subject Device: Strados RESP	**Predicate Device: VitaloJAK K110525**	**Reference: Littmann Model 3200 K083903**
Name	Strados Remote Electronic Stethoscope Platform (RESP)	Vitalograph Model 7100- VitaloJAK	3M™ Littmann® Electronic Stethoscope Model 3200
Manufacturer	Strados Labs, Inc.	Vitalograph (Ireland) Ltd.	3M
Product Code	DSH	DSH	DQD
Regulation Number	21 CFR 870.2800	21 CFR 870.2800	21 CFR 870.1875
Device Classification Name	Recorder, Magnetic Tape, Medical	Recorder, Magnetic Tape, Medical	Stethoscope, Electronic
Device Classification	Class 2	Class 2	Class 2
Indication for Use	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.	The Model 7100 is a non-invasive battery operated device intended to acquire, record and store ambulatory cough sounds from patients for up to 24 hours. The device stores the data on a removable memory card for later playback, review, and analysis of the cough sounds on a windows based PC.	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.
Age of Device Use	Adults.	All ages.	All ages.
Principle of Operation	**Placement** - The Strados RESP is placed by a clinician and adhered to the skin. **Recording** - Lung sounds are recorded by wearable per the App-selected	**Placement**- The VitaloJAK is adhered to skin at the suprasternal notch. **Recording**- A continuous recording is started by a clinician on the device.	**Placement** - The Littmann is placed by clinician similar to a traditional stethoscope.

	Subject Device: Strados RESP	**Predicate Device: VitaloJAK K110525**	**Reference: Littmann Model 3200 K083903**
	recording mode. In a clinical setting, a clinician configures the options and initiates/stops sound capture **Transmission**- Recordings are transmitted to the Strados Mobile App (SMA). Clinician can listen to recordings at any time via the SMA.	**Transmission-** The data is retained on board the device. After all data is collected, the data is transferred via USB cable through a PC to a web portal. **Playback**- No playback is provided to the clinician. Coughs are counted by VitaloJAK personnel. **Use-** The VitaloJAK is not intended for immediate clinical action.	**Recording** - Lung sounds can be recorded by pressing the physical buttons on the device. **Transmission**- Recordings can be transmitted to an external device with custom software. The device can also save up to 12 recordings. **Playback-** Recordings can be played back audibly via the deice speaker and into the device ear pieces.
Condition of Use	Reusable	Reusable	Reusable
Rx or OTC	Prescription Only	Prescription Only	Prescription Only
Wearable	Yes	Yes	No

Clinical Performance Data

Clinical performance testing was performed to validate the quality and fidelity of the subject device's recorded lung sounds.

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 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 includes:
  - Frequency response equivalence testing from 20 to 2000Hz against a reference 510(k) cleared stethoscopes
  - Functional Testing
  - Validation of device cleaning instructions for likely use
  - Ship Testing

The Strados Wearable Device is considered as surface devices in contact with intact skin. The biocompatibility evaluation of the subject device was based on ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. This includes Cytotoxicity, Sensitization and Intracutaneous Reactivity/Irritation testing. All testing was passed.

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.