March 29, 2019

Spry Health, Inc.
% Craig Coombs
Consultant
Coombs Medical Device Consulting, Inc.
1193 Sherman St.
Alameda, CA 94501

Re: K181352
Trade/Device Name: Loop System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, BZQ
Dated: March 4, 2019
Received: March 5, 2019

Dear Craig Coombs:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -S
2019.03.29 10:28:03 -04'00'

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K181352

Device Name
Loop System

Indications for Use *(Describe)*
The Loop System is intended for adult patients in the home environment for passive, non-invasive, intermittent data collection of physiological parameters that will later be transmitted to a web server for remote review by a clinician.

The Loop System measures and records:
• arterial oxygen saturation (SpO2)
• heart rate (HR)
• respiration rate (RR)

All of these measurements are made when no motion is detected by the System.

The Loop System device does not provide physiological alarms

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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"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."

Section 5: 510(k) Summary

A. Device Information

Category	Comments
Sponsor:	Spry Health, Inc 235 Alma St Palo Alto, CA 94301 Tel: (650) 352-3429
Primary Communicant	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140
Device Common Name:	Oximeter Breathing Frequency Monitor
Device Classification Number:	21 CFR 870.2700 21 CFR 868.2375
Device Classification & Product Code:	Class 2, DQA & BZQ
Device Proprietary Name:	Loop System

Predicate Device Information:

Predicate Device:	MightySat RX Fingertip Pulse Oximeter
Predicate Device Manufacturer:	Masimo
Predicate Device Common Name:	Oximeter Breathing Frequency Monitor
Predicate Device Premarket Notification #	K181956
Predicate Device Classification:	21 CFR 870.2700: Oximeter 21 CFR 868.2375: Breathing Frequency Monitor
Predicate Device Class & Product Code:	Class 2, DQA & BZQ

B. Date Summary Prepared

13 March 2019

C. Description of Device

The Loop System is a prescription-only medical device indicated for use by adult patients in the home environment for passive, non-invasive, intermittent data collection of resting (i.e., no motion) physiological parameters. The data is derived from reflectance-based photoplethysmogram (PPG) signals from the patient's wrist, collected by Light Emitting Diodes

(LEDs) of varying wavelengths and photodiodes sensitive to said wavelengths embedded in the Loop Band. An accelerometer incorporated in the Loop Band determines when the patient is at rest by constantly monitoring the activity level of the patient. The data is recorded during those resting periods. Using filtering technology for removal of noise (including ambient light) and data processing algorithms, the Loop System stores the raw data collected until it is able to send to the Spry Server.

Patients wear the Loop Band on their wrist for periods of up to 24 hours. Patients will then have to charge the Loop Band with a Loop Charging Station provided to them as part of the Loop System. During charging, the data is uploaded to the Spry Server.

The Loop band can independently analyze and display resting heart rate and arterial oxygen saturation (SpO2). The data must be downloaded and analyzed by the Spry Server to determine respiration rate.

All physiological measurements collected by the Loop System are reported on a comma separated value (CSV) file as a time-stamped series. The CSV can then be remotely accessed through a web interface for review and analysis by a clinician.

D. Indications for Use

The Loop System is intended for adult patients in the home environment for passive, non-invasive, intermittent data collection of physiological parameters that will later be transmitted to a web server for remote review by a clinician.

The Loop System measures and records:

- arterial oxygen saturation (SpO2)
- heart rate (HR)
- respiration rate (RR)

All of these measurements are made when no motion is detected by the System.

The Loop System device does not provide physiological alarms

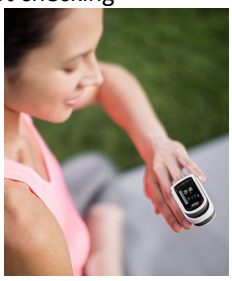
E. Comparison to Predicate Device

The application Spry Health Loop System is substantially equivalent to the Masimo MightySat Rx Fingertip Pulse Oximeter (K181956). The devices have a similar Indications for Use, features, technology and accuracy.

	Predicate Device Masimo MightySat Rx Fingertip Pulse Oximeter K181956	**Application Device Spry Health, Inc. Loop System**	**Impact on Substantial Equivalence**
Intended Use Issues			
Indications for Use	The Masimo MightySat Rx Fingertip Pulse Oximeter is intended for hospitals, hospital-type facilities, home environments, and transport. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused. The Masimo MightySat Rx Fingertip Pulse Oximeter is indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients.	The Loop System is intended for adult patients in the home environment for passive, non-invasive, intermittent data collection of physiological parameters that will later be transmitted to a web server for remote review by a clinician. The Loop System measures and records: • arterial oxygen saturation (SpO2) • heart rate (HR) • respiration rate (RR) All of these measurements are made when no motion is detected by the System. The Loop System device does not provide physiological alarms.	The application Loop System Indications for Use includes a subset of the patients and use conditions cleared in the predicate device. The Loop System and the predicate are intended for adults in a home environment when the wearers are not moving. Since the application device is intended for a subset of the application conditions of the predicated device, no new types of safety or efficacy questions are raised. Both devices provide SpO2, HR, and RR. Neither device is intended for continuous vital sign monitoring.
Product Code **Regulation Description**	DQA - Oximeter BZQ –Breathing Frequency Monitor	DQA – Oximeter BZQ –Breathing Frequency Monitor	Arterial Oxygen saturation and derived HR and RR capabilities all fall under the same product codes for both devices.
Patient Population	HR & SpO2 - Adults, pediatrics Respiratory Rate – Adults Non-critical care	Adult patients for all parameters Non-critical care	The application device intended cohort is a subset of the predicate's; no new types of safety or efficacy questions are raised.

	Predicate Device Masimo MightySat Rx Fingertip Pulse Oximeter K181956	Application Device Spry Health, Inc. Loop System	Impact on Substantial Equivalence
Use Environment	hospitals, hospital-type facilities, home environments, and transport.	home environment	The application device use environment is a subset of the predicate's; no new types of safety or efficacy questions are raised.
Prescribed?	Prescription use only	Prescription use only	Identical
Parameter Sampling Frequency	Spot check parameters as desired by users. Not designed for continuous wearing.	Designed for nearly continuous measuring and recording of physiological data when the patient is not in motion	Difference in sampling frequency does not raise new safety or efficacy questions
Technology associated with each parameter			
Respiration Rate Fundamental Scientific Technology	Respiration rate (RR) measured by analyzing cyclic variations in the photoplethysmogram. The diodes are mounted in the device such that they are in contact with the skin.	Same	Technologically equivalent
Respiration Rate Range	4 – 70 respirations per minute (RPM)	4 - 40 RPM	Application device has a lower upper limit than predicate. Specific RPMs that are >40 are not clinically differentiating in a retrospective monitoring context
Respiration Rate Accuracy	3 RPM A_{RMS}	3 RPM A_{RMS}	A clinical study demonstrated that the Loop System could accurately monitor respiration rate as well as the predicate, within the sensor range
Arterial hemoglobin oxygen saturation (SpO2) Fundamental Scientific Technology	SpO2 measured by analyzing reflectance of certain LED frequencies in a photoplethysmogram design. The diodes are mounted in the device such that they are in contact with the skin.	Same	Technologically equivalent

	Predicate Device Masimo MightySat Rx Fingertip Pulse Oximeter K181956	Application Device Spry Health, Inc. Loop System	Impact on Substantial Equivalence
SpO2 Range	70 – 100%	70 – 100%	Identical
SpO2 Accuracy	2% A_{RMS}, no motion	3% A_{RMS}, no motion	Both comply with ISO 80601-2-61 as well as with FDA Guidance for Pulse Oximeters (2013)
Heart Rate (HR) Fundamental Scientific Technology	HR measured by analyzing cyclic variations in reflectance of certain LED frequencies in a photoplethysmogram design. The diodes are mounted in the device such that they are in contact with the skin.	Same	Technologically equivalent
Heart Rate Range	25 – 240 beats per minute (BPM)	25 – 250 beats per minute (BPM)	Clinically equivalent. Both comply with ISO 80601-2-61
Heart Rate Accuracy	3 BPM ARMS, no motion	3 BPM ARMS, no motion	Clinically equivalent. Both comply with ISO 80601-2-61
Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-61 ISO 10993-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1 -6 ISO 80601-2-61 ISO 10993-1	Both devices meet latest guidelines for safety and efficacy
Design			
User Interface	Finger clamp	Wrist band	Both devices are worn to provide device access to peripheral arteries. Difference in particular user interface does not raise new questions of safety or efficacy.

	Predicate Device **Masimo MightySat Rx Fingertip Pulse Oximeter** **K181956**	**Application Device** **Spry Health, Inc.** **Loop System**	**Impact on Substantial Equivalence**
Wearing location and frequency	For intermittent wearing, aka "spot checking" 	Continuous wearing, nearly continuous recording of all data. 	Difference in wearing location on the body and frequency does not raise new questions of safety or efficacy. Both locations allow for monitoring peripheral arteries.
Display	OLED color display of HR and SpO2 when device worn 	LED color display of HR and SpO2 on demand 	Similar
Power source	2 AA batteries	Internal rechargeable batteries	Both battery-powered
Data Communication	Wireless (Bluetooth pairing) with mobile devices such as smartphones	Wireless (cellular connection) via charging station to Spry Server.	Both devices are designed to transmit their data to alternate devices or sites.
Type of protection	Unknown	Type BF – Applied Part per IEC 60601-1	Application device meets latest guidelines for electrical safety
Patient contracting materials	Plastic	Plastic	Similar
Biocompatibility	Compliant to ISO 10993-1	Compliant to ISO 10993-1	Identical

F. Summary of Supporting Data

Spry Health has conducted extensive testing to ensure that the Loop System met design specifications, functions as intended, and conforms to internationally recognized standards and FDA Guidelines.

Bench Testing

All test results demonstrate the performance of Spry Health Loop System met the requirements of its pre-defined acceptance criteria and intended use. The results of the bench (non-clinical) testing demonstrate that the Loop System is as safe and effective as the predicate device.

Bench testing demonstrated the accuracy of the heart rate monitoring with the Loop System. This testing was conducted in accordance with ISO 80601-2-61 *Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment* and in accordance with the FDA Guidelines for *Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff* (2013). The Loop System was found to be in compliance with both documents.

Additionally, transit testing and one-year shelf life testing was conducted.

Electrical Safety and Electromagnetic Compatibility Testing

Electrical safety testing was conducted in accordance with:
IEC 60601-1:2005+AM1:2012 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014: *Medical Electrical Equipment – Part 1-2: General Requirements for* Safety – Collateral standard: Electromagnetic Disturbances – Requirements and tests

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 60601-1-6:2013 *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

The Spry Health Loop System passed all electrical safety and EMC testing.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009/AC:2010, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and FDA's guidance documents, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued June 16, 2016. This testing demonstrates that the materials in the Loop Band will not cause an adverse biocompatibility reaction when used as intended.

Clinical Studies

Two clinical studies were conducted to demonstrate the performance of the Loop System.

One clinical study investigated the accuracy of respiration rate monitoring in 12 healthy adult subjects with a range of skin types and respiratory rates. The Loop System accuracy was shown to be equivalent to a gold standard monitoring procedure.

Another clinical study investigated the accuracy of the pulse oximetry monitoring in 12 healthy adult subjects with a range of skin types. The Loop System accuracy was compared to the gold standard, arterial blood gas analysis.

This testing was conducted in accordance with ISO 80601-2-61 *Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment* and in accordance with the FDA Guidelines for *Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff* (2013). The Loop System was found to be in compliance with both documents.

G. Conclusion

Spry Health concludes that the application Spry Health Loop System is substantially equivalent to the Masimo MightySat Rx Fingertip Pulse Oximeter (K181956). The devices have a similar Indications for Use, features, technology and accuracy in monitoring respiration rate, heart rate and pulse oximetry saturation.