June 05, 2020

Spire, Inc. d/b/a Spire Health
% Jared Seehafer
Regulatory Consultant
Enzyme Corporation
360 Langton St, Ste 100
San Francisco, California 94103

Re: K192952
Trade/Device Name: Spire Health Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, BZQ, DRG, LEL
Dated: April 23, 2020
Received: April 27, 2020

Dear Jared Seehafer:

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

Jennifer Shih
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192952

Device Name
Spire Health Remote Patient Monitoring System

Indications for Use *(Describe)*
The Spire Health Remote Patient Monitoring System is intended for reusable bedside and mobile multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The Spire Health Remote Patient Monitoring System is intended for longitudinal monitoring of the following parameters in adults:
- Pulse Rate
- Respiratory Rate
- Sleep/Wake Behavior
- Activity associated with Movement

The Spire Health Remote Patient Monitoring System is intended only for general, non-diagnostic sleep and wake behavioral monitoring. It is not intended to assess sleep staging nor diagnose sleep disorders.

The Spire Health Remote Patient Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The Spire Health Remote Patient Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG.

The Spire Health Remote Patient Monitoring System is not a substitute for an ECG monitor.

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.

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5 510(k) Summary

Table 5-1. Subject Device Overview.

Submitter's Name:	Spire, Inc.
Address:	2030 Harrison St San Francisco, CA 94110
Contact Person:	Jared Seehafer
Title:	Regulatory Consultant
Telephone Number:	415-638-9554
Fax Number:	415-367-1279
Email:	jared@enzyme.com
Date Summary Prepared:	4-JUN-2020
Device Proprietary Name:	Spire Health Remote Patient Monitoring System
Common Name:	System, Network and Communication, Physiological Monitors
Regulation Number:	21 CFR 870.2300
Regulation Name:	Cardiac Monitor
Product Code:	MSX
Subsequent Product Codes:	BZQ, LEL
Device Class:	Class II
Primary Predicate Device	Trade name: Current Wearable Health Monitoring System Manufacturer: Current Health Playfair House, 12A Broughton Street Lane Edinburgh, EH1 3LY Gb Regulation Number: 21 CFR 870.2300 Regulation Description: Cardiac Monitor Device Class: Class II Product Code: MSX Subsequent Product Codes: DQA, FLL, BZQ, DRG 510(k) Number: K190073
Secondary Predicate Device	Trade name: ActiGraph Gt9x-Link (originally cleared under trade name ActiTrainer) Manufacturer: ActiGraph Regulatory Number: 21 CFR 890.5360 Regulation Description: Measuring exercise equipment Product Code: ISD 510(k) Number: K080545

5.1 Device Description

The Spire Health Remote Patient Monitoring System (RPM) is designed to capture, process, and longitudinally track clinically relevant patient health data and share this data with healthcare providers with a view to improving patient health and outcomes. The RPM is intended for longitudinal monitoring of pulse rate, respiratory rate, sleep/wake behavior, and activity associated with movement.

The RPM solution is comprised of four components - a Medical Health Tag (MHT), a Spire Mobile Application (Mobile App), a Cloud Platform (Platform) and a Healthcare Professional Dashboard (HPD). The patient facing components of the system (the MHT and Mobile App) are intended for daily use in professional healthcare facilities or in the home. The MHT is a component designed to be affixed semi-permanently via an adhesive backing to the patient's first layer of clothing (e.g. underwear, bras, or pajamas), passing through laundry cycles without detaching. It does not require charging by the user.

5.2 Indications for Use

The Spire Health Remote Patient Monitoring System is intended for reusable bedside and mobile multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities or their own home. It is intended for monitoring of patients by trained healthcare professionals.

The Spire Health Remote Patient Monitoring System is intended for longitudinal monitoring of the following parameters in adults:

- Pulse Rate
- Respiratory Rate
- Sleep/Wake Behavior
- Activity associated with Movement

The Spire Health Remote Patient Monitoring System is intended only for general, non-diagnostic sleep and wake behavioral monitoring. It is not intended to assess sleep staging nor diagnose sleep disorders.

The Spire Health Remote Patient Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.

The Spire Health Remote Patient Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG.

The Spire Health Remote Patient Monitoring System is not a substitute for an ECG monitor.

5.3 Summary of Substantial Equivalence

The following table demonstrates equivalence between the Subject and Predicate Devices.

Table 5-2. Subject and Predicate Devices Comparison.

Topic	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
Common Name	System, Network and Communication, Physiological Monitors	System, Network and Communication, Physiological Monitors	Exerciser, Measuring	N/A
Device Manufacturer	Spire, Inc.	Current Health Ltd.	ActiGraph LLC	N/A
Device Classification	2	2	2	N/A
510(k) Number	N/A	K190073	K080545	N/A
Primary Product Code	MSX	MSX	ISD	Though the ActiGraph Gt9x-Link (K080545) was cleared under product code ISD, regulation 21 CFR 890.5360, Spire proposes that the Spire RPM's secondary product code be LEL, regulation 21 CFR 882.5050, as the regulation description and product code better match the functionality of both the ActiGraph product and the Spire product. The latest version of the ActiGraph product, the CentrePoint

Topic	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
				Insight Watch (K181077), similarly made this transition. Though it is substantially equivalent to the ActiGraph Gt9x-Link (K080545), it is cleared under a different product code & regulation (i.e. LEL instead of ISD).
Secondary Product Code	BZQ, LEL	FLL, DQA, BZQ, DRG	N/A	N/A
Target Population	Adult	Adult	Adult	Subject and Predicates are identical
Environment	Professional Health Care Facilities and Home	Professional Health Care Facilities and Home	Professional Health Care Facilities and Home	Subject and Predicates are identical
Intended Use/ Indications for Use	The Spire Health Remote Patient Monitoring System is intended for reusable bedside and mobile multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Spire Health Remote Patient Monitoring System is intended for longitudinal	The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and	The ActiTrainer is a small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. The ActiTrainer can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	Subject and Predicates differ only in that: 1) the Subject Device measures a subset of the parameters that the Primary Predicate Device does, while additionally measuring additionally measuring an additional parameter: hours asleep and hours awake, referenced herein simply as “Sleep/Wake”. This parameter is measured by the Secondary Predicate Device. 2) the Subject device is

Topic	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
	monitoring of the following parameters in adults: • Pulse Rate • Respiratory Rate • Sleep/Wake Behavior • Activity associated with Movement The Spire Health Remote Patient Monitoring System is intended only for general, non-diagnostic sleep and wake behavioral monitoring. It is not intended to assess sleep staging nor diagnose sleep disorders. The Spire Health Remote Patient Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms. The Spire Health Remote Patient Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients,	audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults: • Pulse rate • Oxygen saturation • Temperature • Movement The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring of respiration rate, non-invasive blood pressure and weight in adults. The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms. The Current Wearable Health Monitoring System is not intended for use on acutely ill		intended for longitudinal monitoring, i.e. ongoing monitoring at discrete time intervals (i.e. every hour, every day, every week, every month), while the Primary Predicate device is intended for continuous monitoring of some physiological parameters and intermittent monitoring of others.

Topic	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
	they should be monitored using a device with continuous ECG. The Spire Health Remote Patient Monitoring System is not a substitute for an ECG monitor.	cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor. The Current Wearable Health Monitoring System is not intended for SpO2 monitoring in conditions of high motion or low perfusion.		
Sensor Types	Pulse Rate: Photoplethysmography (PPG) Respiratory Rate: Force sensor Activity associated with Movement: Accelerometer Sleep/Wake: Accelerometer + Force sensor	Pulse Rate: PPG Respiratory Rate: PPG Movement: Accelerometer	Activity associated with Movement: Accelerometer Sleep/Wake: Accelerometer	Subject and Primary Predicate Device use identical methods to sense Pulse Rate and Movement. Subject and Primary Predicate Device use different methods for Respiratory Rate. However, both Subject and Primary Predicate device validate Respiratory Rate accuracy in the same manner. The Subject Device measures an additional parameter, Sleep/Wake Behavior, using a sensor that is common to both

Topic	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comment
				Subject and Primary Predicate, a triaxial accelerometer. Secondary Predicate and Subject Device both use an Accelerometer to measure activity and sleep/wake behavior. Subject Device additionally utilizes a force sensor as input to analysis of sleep/wake behavior.

5.3 Technological Characteristics

A review of the Spire Health Remote Patient Monitoring System with the predicate devices found that the technology, mode of operation, and general principles for treatment with this device were substantially equivalent as the predicate devices. See Table 5-2 for a comparison of technological characteristics between the three devices.

5.4 Performance Data

The Spire Health Remote Patient Monitoring System was evaluated using the following testing:

Table 5-3. Summary of Testing.

Test Name	**Test Description**	**Results**
Electrical Safety	The RPM was tested to demonstrate compliance to the standards for basic safety and essential performance for Medical Electrical Equipment (IEC 60601-1)	PASS
EMC	The RPM was tested to demonstrate compliance to the applicable standards for electromagnetic compatibility (IEC 60601-1-2)	PASS
Biocompatibility	The RPM was tested to demonstrate biocompatibility per ISO 10993-1	PASS
Usability/Human Factors	The RPM was assessed per IEC 62366 to demonstrate usability	PASS
Alarms	The RPM was assessed to demonstrate compliance to IEC 60601-1-8	PASS
Ship/Transport	The RPM and its packaging was tested to demonstrate compliance to ISTA 3A	PASS
Pulse Rate Validation	The RPM was tested to confirm the accuracy of pulse rate monitoring of the system in accordance with ISO 80601-2-61	PASS
Respiratory Rate Validation	The RPM was clinically tested in comparison to end-tidal CO2 to confirm the accuracy respiration rate measurement	PASS
Activity associated with Movement Validation	The RPM was clinically tested to confirm the accuracy of the activity tracking.	PASS
Environment	The RPM was tested to confirm the storage and operating temperature ranges.	PASS
Wash/Dry	The MHT was tested to confirm performance after wash/dry cycles	PASS

Shelf Life	The MHT was tested utilizing accelerated aging to support shelf life claims	PASS
Battery	The battery life of the MHT was tested while operating in various modes	PASS
Software Verification and Validation	Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaw could directly result in minor injury to the patient or operator or a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.	PASS

Based upon the results of this testing, the Spire Health Remote Patient Monitoring System performance was determined to be substantially equivalent to the predicate devices.

5.5 Substantial Equivalence Conclusion

Spire Health Remote Patient Monitoring System is substantially equivalent to the legally marketed primary predicate device, Current Wearable Health Monitoring System (K190073). The two devices have similar intended uses. The technological differences between the devices do not raise any new questions of safety or effectiveness.