March 24, 2022

Graftworx, Inc. dba Alio
Allison Komiyama, PhD, RAC
Principal Consultant
RQM+
2251 San Diego Ave. Suite B-257
San Diego, California 92110

Re: K211365
Trade/Device Name: Alio Medical Remote Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DQD
Dated: March 21, 2022
Received: March 23, 2022

Dear Allison Komiyama:

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,

Jennifer Shih Kozen
Assistant Director
External Heart Rhythm and Rate Team
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)*
K211365

Device Name
Alio Medical Remote Monitoring System

Indications for Use *(Describe)*
The Alio Medical Remote Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals to intermittently collect physiological data in home use settings. The data includes skin temperature, auscultation sound data and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the healthcare provider's (HCP) review.

The Alio Medical RMS is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to measure skin temperature and pulse rate where clinically indicated. The SmartPatch sensor is indicated to record and transmit auscultation sound data where clinically indicated.

The device is not intended for use in critical care or other high-acuity environments. The Alio Medical RMS is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

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. General Information

510(k) Sponsor	Alio, Inc.
Address	544B Bryant St San Francisco, CA 94107
Correspondence Person	Allison C. Komiyama, Ph.D., R.A.C. RQM+
Contact Information	Email: akomiyama@rqmplus.com Phone: +1 (412) 816-8253
Date Prepared	March 24, 2022

2. Proposed Device

Proprietary Name	Alio Medical Remote Monitoring System
Common Name	Alio Medical RMS
Classification Name	Radiofrequency physiological signal transmitter and receiver
Regulation Number	21 CFR 870.2910
Product Code	DRG, DQD
Regulatory Class	II

3. Predicate Device

Proprietary Name	Vital Connect Platform
Premarket Notification	K152139
Classification Name	Radiofrequency physiological signal transmitter and receiver
Regulation Number	21 CFR 870.2910
Product Code	DRG, DSI, MHX
Regulatory Class	II

4. Reference Device

Proprietary Name	Eko Core
Premarket Notification	K200776
Classification Name	Stethoscope
Regulation Number	21 CFR 870.1875
Product Code	DQD
Regulatory Class	II

5. Reference Device

Proprietary Name	BB-613 WP
Premarket Notification	K190792
Classification Name	Oximeter, non-invasive blood pressure measurement system
Regulation Number	21 C.F.R. 870.2700 Oximeter, 870.1130 Noninvasive blood pressure measurement system
Product Code	DQA, DXN, DRG
Regulatory Class	II

6. Device Description

Alio Medical Remote Monitoring System, or "Alio Medical RMS", utilizes a wearable device (SmartPatch) on the skin to gather physiological data and then transmits it to a device (Bedside Hub) located in the subject's home. The Bedside Hub then relays this raw data to the Alio Medical Cloud where it is processed and analyzed using Alio's proprietary algorithms. Data is accessible to Healthcare Professionals and the Alio clinical team via a web-based Clinician Portal. The SmartPatch and Bedside Hub are intended to be used on general care patients who are 18 years of age or older in a non-clinical environment. The web-based Clinical Portal is to be used by healthcare professionals in an office environment.

The Alio Medical Remote Monitoring System includes the following components:

- SmartPatch
- Bedside Hub
- Alio Medical Cloud (backend only - not user facing)
- Clinician Portal

SmartPatch

A flexible, silicone-encased patch that can be worn where clinically indicated for up to seven days at a time. It houses numerous sensor technologies, which include a microphone, accelerometer, temperature sensors, and a PPG sensor. The sensors collect physiological data including skin temperature, auscultation sound data, and heart rate. Data is transmitted to the Cloud, via the Hub, where it is analyzed and sent to a Healthcare Professional via the Web Portal.

Bedside Hub

The Bedside Hub has the form and finish of an at-home device. It automatically communicates with the activated SmartPatch and uploads physiological data to the Alio Medical Cloud.

Alio Medical Cloud

The Cloud features a database that supports storage, analytics, system monitoring and visualization capabilities. The Alio Medical Cloud is encrypted and HIPAA compliant. All patient data is fully traceable to device and patient ID via the database.

Clinician Portal

The Clinician Portal is the interface tool between a user (healthcare professional users only) and the system that enables the user to visualize and interact with data being generated by the system.

Note - none of the above components/accessories of the Alio Medical RMS have received prior 510(k) clearance.

7. Intended Use/ Indications for Use

The Alio Medical Remote Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals to intermittently collect physiological data in home use settings. The data includes skin temperature, auscultation sound data and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the healthcare provider's (HCP) review.

The Alio Medical RMS is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to measure skin temperature and pulse rate where clinically indicated. The SmartPatch sensor is indicated to record and transmit auscultation sound data where clinically indicated.

The device is not intended for use in critical care or other high-acuity environments. The Alio Medical RMS is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.

8. Substantial Equivalence

Feature/ Function	Device: Alio Medical RMS	Predicate Device: Vital Connect Platform (K152139)
Indications for Use	The Alio Medical Remote Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals to intermittently collect physiological data in home use settings. The data includes skin temperature, auscultation sound data and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the healthcare provider's (HCP) review. The Alio Medical RMS is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to measure skin temperature and pulse rate where clinically indicated. The SmartPatch sensor is indicated to record and transmit auscultation sound data where clinically indicated. The device is not intended for use in critical care or other high-acuity environments. The Alio Medical RMS is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.	The Vital Connect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the Vital Connect Sensor for storage and analysis. The Vital Connect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the Vital Connect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.
Rx or OTC	Rx	Rx
Intended Users	Adult - 18+	Adult - 18+
Intended Environment	Home	Home & healthcare settings
Application	Patch - SmartPatch only	Patch
Single-use	Yes - SmartPatch only	Yes - patch only

Data transmitted	Skin temperature Electronic stethoscope for sound auscultation data Heart rate	- heart rate - ECG - heart rate variability - R-R interval - respiratory rate - skin temperature - activity (including step count) - posture (body position relative to gravity including fall)
Sensor Type	Thermistor Microphone Accelerometer PPG	- ECG electrodes to detect heart rate - 3-axis MEMS accelerometer to detect motion - Thermistors to detect body temperature
Temperature Data	Skin temperature 15°C – 50°C	Skin temperature 15°C – 50°C
Sound Data	- heart - lungs - bowel - arteries - veins	N/A
Sound Amplification	Yes	N/A
Record and Playback Sound	Yes (Playback via Clinician Portal)	N/A
Operating Mode	Intermittent	Continuous
Data Transmission	Bluetooth - SmartPatch only Radio Frequency: 2.4 - 2.5 GHz (Cellular) - SmartHub only	Bluetooth
Energy Source	SmartPatch only - battery (Li-ion) Hub - 5V Mains DC	Sensor only - battery (Li-ion)
Standards	IEC 60601-1 3rd ed. IEC 60601-1-11:2010 IEC 80601-2-56:2017 IEC 80601-2-61:2017 IEC 62471:2008 IEC 60529:2013 IEC 60086-4:2019 IEC 60601-1-2:2007/2014 IEC 62304:2006/A1:2016 IEC 62366-1:2007/2015 FCC CRF47 Part 15 Subpart B ISO 10993-5:2009 ISO 10993-10:2010	ISO 10993-1:2009 IEC 60601-1 IEC 60601-1-11 IEC 60601-1-6 IEC 60601-2-25 IEC 60601-2-47 IEC 60601-1-2 IEC/TS 62657-2 FCC CRF47 Part 15 Subpart C

Technological Characteristic Comparison with Reference Devices

Feature/ Function	Device: Alio Medical RMS	Reference Device: BioBeat BB-613P (K190792)
Application	Skin - SmartPatch only	Wrist area and skin
Monitoring	Intermittent	Spot Check/Intermittent
Principle of Operation	Pulse reflectance technology. Light source is comprised of 6 LEDs (2x green, 2x red, 2x IR), reflected light is detected by 4 photodiodes. An accelerometer provides additional heart rate data.	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time (PWTT) which is obtained utilizing pulse measurements from the integrated skin attached SpO2 sensor
Emitted light peak wavelength	530 nm (Green), 650 nm (Red), 940 nm (IR)	880nm (IR), 650nm (Red)
Measurement Range, HR	30-200 bpm	40-250bpm
A_{rms}, HR	5 bpm	±3%
Application Method	Biocompatible adhesive patch	Biocompatible adhesive patch

Feature/ Function	Device: Alio Medical RMS	Reference Device: EKO Device (K200776)
Stethoscope Type	Standalone electronic stethoscope	Attachment to an analog stethoscope
Auscultation Data	Yes	Yes
Measurement Frequency Range	55 - 2000 Hz	unknown
Sound Amplification	Yes	Yes
Connectivity	Bluetooth	Bluetooth
Record and Save	Yes	Yes

9. Performance Data

Nonclinical verification and validation test results established that the device meets its design requirements and intended use, that it is as safe, as effective, and performs as well as the predicate devices, and that no new issues of safety and effectiveness were raised. The Alio

Medical RMS was designed, verified, and validated according to the company's Design Control process and has been subjected to extensive safety and performance testing as shown in the test results provided in this submission. Verification and Validation testing data demonstrate that the device meets all of its specifications including compliance with the following standards:

Safety

- IEC 60601-1 3rd Ed.
- IEC 60601-1-11:2010
- IEC 80601-2-56:2017
- IEC 80601-2-61:2017
- IEC 62471:2008
- IEC 60529:2013
- IEC 60086-4:2019

EMC

- IEC 60601-1-2:2007/2014
- FCC Part 15 Radio Frequency Devices, Subpart B - Unintentional Radiators

Software

- IEC 62304:2006/A1:2016
- FDA Guidance document, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

Usability

- IEC 62366-1:2007/2015
- FDA Guidance document, *"Applying Human Factors and Usability Engineering to Medical Devices"*

Biocompatibility

- ISO 10993-5:2009
- ISO 10993-10:2010

10. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, Alio Medical Remote Monitoring System raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.