March 17, 2023

Alio, Inc.
% Kevin Go, MBA, RAC, CQA
Regulatory Consultant
RQM+
2790 Mosside Boulevard, Suite 800
Monroeville, Pennsylvania 15146

Re: K223073
Trade/Device Name: Alio
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: II
Product Code: DRG, DQD
Dated: February 15, 2023
Received: February 15, 2023

Dear Kevin Go:

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,

Gema Gonzalez -S

Gema Gonzalez, MS
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K223073

Device Name
Alio

Indications for Use *(Describe)*
Alio is a wireless remote monitoring system intended for use by healthcare providers (HCP) to collect physiological data in clinical and non-clinical settings. The data includes measured hemoglobin (Hgb) and hematocrit (Hct), skin temperature, auscultation sound data, and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the HCP's review.

The data also include a qualitative indicator of abnormal levels of potassium derived from relative variability of photoplethysmography waveforms and medically accepted threshold values.

Alio is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to provide measurement of heart rate, skin temperature, Hgb, Hct and a qualitative risk assessment of the patient having an abnormal potassium level. The SmartPatch sensor is indicated to record and transmit auscultation sound data. For qualitative assessment of abnormal potassium levels, and quantitative measurement of heart rate, skin temperature, Hgb and Hct, the SmartPatch should be placed on an arm based arteriovenous access on patients with end stage kidney disease (ESKD).

Alio is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices. Therapeutic management decisions, including management of dyskalemia, should be made based on a complete assessment of the patient's condition and should not be based solely on Alio.

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

DATE PREPARED
March 17, 2022

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DEVICE INFORMATION

Proprietary Name/Trade Name:	Alio
Common Name:	Alio
Regulation Number:	21 CFR 870.2910
Class:	Class II
Product Code:	DRG, DQD

PREDICATE DEVICE IDENTIFICATION
Alio is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate/Reference*
K211365	Alio Medical Remote Monitoring System	Predicate
K182887	Masimo Rad-67 Pulse CO-Oximeter and Accessories	Reference
K181956	Masimo MightSat Pulse Oximeter	Reference
K142209	Pulse oximeter NBM-200	Reference
K193626	Masimo Rad-97 Pulse CO-Oximeter and Accessories	Reference

DEVICE DESCRIPTION
Alio is a wireless remote monitoring system intended for use by healthcare providers (HCP) to collect physiological data in clinical and non-clinical settings. Alio is intended to be used on general care patients and patients with end stage kidney disease (ESKD), who are 18 years of age

or older in clinical and non-clinical settings. Alio includes the following components:

- Alio SmartPatch

The Alio SmartPatch is a flexible, silicone-encased patch designed to be worn between the cannulation sites of the arteriovenous (AV) fistula or graft for up to seven days. It houses numerous sensor technologies which collect data for the derivation of physiologic parameters including hemoglobin, hematocrit, an assessment of normal or abnormal (hyper or hypokalemic) levels of serum potassium (K+), skin temperature, auscultation sound data, and heart rate. The data from the sensors is transmitted from the SmartPatch to the Alio Hub via a bluetooth connection. The data is then transmitted to the Alio Cloud, via the Alio Hub, where it is analyzed and made available to a clinical care team via the Alio Portal.

- Alio Hub

The Alio Hub is designed for use in clinical and non-clinical use settings. It automatically communicates with the activated Alio SmartPatch via Bluetooth and uploads physiological data to the Alio Cloud via cellular connection.

- Alio Cloud

The Alio Cloud allows clinicians to access patient data collected via the Alio SmartPatch and wirelessly transferred from the Alio Hub to the secure server (the Alio Cloud).

- Alio Portal

The Alio Portal stores data received from the Alio Hub in an Alio Cloud database that supports storage, analytics, system monitoring and visualization capabilities. This data is encrypted and HIPAA compliant. The Alio Portal also serves as the interface with the HCP who can then visualize and interact with data being generated by the system.

INDICATIONS FOR USE

Alio is a wireless remote monitoring system intended for use by healthcare providers (HCP) to collect physiological data in clinical and non-clinical settings. The data includes measured hemoglobin (Hgb) and hematocrit (Hct), skin temperature, auscultation sound data, and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the HCP's review.

The data also include a qualitative indicator of abnormal levels of potassium derived from relative variability of photoplethysmography waveforms and medically accepted threshold values.

Alio is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to provide measurement of heart rate, skin temperature, Hgb, Hct and a qualitative risk assessment of the patient having an abnormal potassium level. The SmartPatch sensor is indicated to record and transmit auscultation sound data. For qualitative assessment of abnormal potassium levels, and quantitative measurement of heart rate, skin temperature, Hgb and

Hct, the SmartPatch should be placed on an arm based arteriovenous access on patients with end stage kidney disease (ESKD).

Alio is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices. Therapeutic management decisions, including management of dyskalemia, should be made based on a complete assessment of the patient's condition and should not be based solely on Alio.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Alio, Inc. believes that Alio is substantially equivalent to the predicate devices based on the information summarized here:

Alio received previous clearance as the Alio Remote Monitoring System in K211365. This submission introduces several changes to the previously cleared device including:

- Expanding the indications for use to include measurements of hemoglobin (Hgb) and hematocrit (Hct) and a qualitative indicator of abnormal potassium levels. Additionally, the device is being indicated for both clinical and non-clinical settings.
- Addition of an artificial intelligence/machine learning (AI/ML) algorithm used in the calculation of the new physiologic parameters
- Modification of the adhesive used to secure the device to the patient
- Minor cosmetic dimensional changes to the Alio SmartPatch

Alio and Alio Medical Remote Monitoring System (K211365) have the same intended use and similar indications, technological characteristics and principles of operation. The differences described above do not present any new issues of safety or effectiveness and have undergone non-clinical and clinical testing to ensure the device is as safe and effective as the predicates.

SUMMARY OF NON-CLINICAL TESTING

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. Alio 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/A1:2015
- 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
- ISO 10093-23:2021

SUMMARY OF CLINICAL TESTING

An IRB-approved clinical study has been conducted to validate the ability of Alio to quantify the new measurements and support the proposed expanded indications. Alio was studied in a multi-center, prospective study with 125 subjects. The purpose of this investigational study is to establish the accuracy of Alio in the assessment of abnormal potassium levels, and measurement of Hgb and Hct, compared to the standard of care blood results and heart rate.

The clinical validation study evaluated patients within the defined Hgb and Hct reference ranges (7-15 g/dL Hgb, 21-45% Hct) with only a single value recorded outside the ranges. The results of the study demonstrate that Alio can accurately assess abnormal potassium levels and measure hemoglobin (Hgb) and hematocrit (Hct) when placed on an arteriovenous access site in patients with ESKD. The results further confirm that Alio can still accurately measure heart rate and record auscultation sound data at the new location. In conclusion, the results of this IRB study support the safety and efficacy of the device for the clinical intended use.

CONCLUSION

Based on the information submitted in this premarket notification, and based on the indications

for use, technological characteristics and performance testing, Alio raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices in terms of safety, efficacy, and performance