February 6, 2023

Vivify Health, Inc.
% Jodi Scott
Partner
Hogan Lovells, US LLP
555 Thirteenth Street, NW
Columbia Square
Washington, District of Columbia 20004

Re: K222398
Trade/Device Name: Care Team Portal
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: January 9, 2023
Received: January 9, 2023

Dear Jodi Scott:

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 Shruti N. Mistry -S

Jennifer Shih Kozen
Assistant Director
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222398

Device Name

Care Team Portal

Indications for Use *(Describe)*

The Care Team Portal is intended to support management of health conditions. It allows a clinical user to configure the collection of patient data. The Care Team Portal includes the ability to notify the patient and the clinical user when the parameters fall outside set limits and customize patient specific recommendations.

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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510(k) Summary

1. General Information

510(k) Sponsor	Vivify Health Inc. 7201 Bishop Rd. Suite #E200 Plano, TX 75024
Submitter	Tracey Fox, Sr. Director Regulatory Affairs tracey.fox@optum.com 763-330-9208
Additional Correspondent	Jodi Scott, Partner jodi.scott@hoganlovells.com 303 454 2463
Date Prepared	5 August 2022

2. Device Identification

Trade Name	Care Team Portal
Common Name	Remote Patient Monitoring System
Product Code	DRG - Transmitters and Receivers, Physiological signal, Radiofrequency
Regulation Number	870.2910 - Radiofrequency physiological signal transmitter and receiver
Device Class	II

3. Predicate Information

Trade Name	eCare Coordinator
510(k) Number	K171029
Product Code	DRG - Transmitters and Receivers, Physiological signal, Radiofrequency
Regulation Number	870.2910 - Radiofrequency physiological signal transmitter and receiver
Device Class	II

4. Device Description

Vivify Remote Patient Monitoring consists of the Care Team Portal, patient portals, and accessory devices.

The Care Team Portal allows the clinical user to view and manage patient information. The functionality includes the ability to add new users and patients, ability to schedule video visits, secure in-app messaging, configure the collection of patient data leveraging care pathways survey questions, educational content and videos with customized notifications, and prioritize patients. It provides a dashboard view of the patients being monitored.

The patient portals enable the patient to provide subjective symptom or health status information that assists the care team in supporting the management of health conditions:

+Home is an option that provides the patient with software pre-loaded on a tablet that allows them to navigate through care pathways for the collection of patient data and view educational content related to their health condition.
+Go is designed for patients to download the software to their own mobile device to navigate through care pathways for the collection of patient data and delivery of educational content related to their health condition.
+Voice allows patients to answer their pathways questions and enter data using their phone.

Accessory devices can be connected to the system to allow for collection of vital signs or used independently to allow for manual input.

5. Indications for Use

The Care Team Portal is intended to support management of health conditions. It allows a clinical user to configure the collection of patient data. The Care Team Portal includes the ability to notify the patient and the clinical user when the parameters fall outside set limits and customize patient specific recommendations.

6. Substantial Equivalence

	Vivify Care Team Portal	Philips (Visicu) eCare Coordinator K171029	Comparison
Product Code	DRG	DRG	Same
Indications for Use	The Care Team Portal is intended to support management of health conditions. It allows a clinical user to configure the collection of patient data. The Care Team Portal includes the ability to notify the patient and the clinical user when the parameters fall outside set limits and customize patient specific recommendations.	eCare Coordinator and its accessories are indicated for use by patients and by care teams for collecting and reviewing patient data from patients who are capable and willing to engage in use of this software, to transmit medical and non-medical information through integrated technologies.	Substantially equivalent – minor wording differences. The indications for use of the proposed device fall within the intended use of the predicate device to provide patient information from the patient location through networking technology to a remote care team.
Fundamental Technology	Software Only	Software Only	Same
Patient Population	Home users	Home users	Same
User Interfaces	Care Team Portal; Patient Portal	Clinical (eCC) and Patient (eCP)	Same
Biometric Parameters	Blood Pressure Weight Blood Glucose Oxygen Saturation Temperature Pulse Rate	Blood Pressure Weight Blood Glucose Oxygen Saturation Temperature Pulse Rate	Same
Alarm Functionality	None	None	Same

	Vivify Care Team Portal	Philips (Visicu) eCare Coordinator K171029	Comparison
Overall Score	Health index score based on biometric measurements, survey responses, and alerts.	Sum of weighted scores for: Measurements, survey responses, issues, readmission risk and days since discharge.	Substantially equivalent – proposed device uses biometric measurements, survey responses, and alerts in the equation.
Intervention rules/ Flags	Used to trigger notifications (flags) to clinician. Customizable by institution or clinician.	Used to trigger notifications (flags) to clinician. Customizable by institution or clinician.	Same
Data Collection	Wireless Bluetooth and manual entry	Wireless Bluetooth and manual entry	Same
Pathways	Clinical users have the option of utilizing the library of Pathways available from Vivify, they may request Vivify to create a custom pathway for them, or they may customize a pathway and create patient specific recommendations.	Used to set patient tasks, surveys and intervention rules. Customizable by institution or clinician	Substantially equivalent – proposed device allows for use of library of pathways or customization through available questions.
Surveys	Clinical users have option to send surveys to patients	Clinical users have option to send surveys to patients	Same
Reports	Patient Summary report and a variety of system administration reports available.	Hard copy patient record report and system administration reports.	Substantially equivalent – proposed device provides similar reporting options.
Video Calls	Capability to schedule and conduct video calls with care providers	Capability to schedule and conduct video calls with care providers	Same
Educational Videos	Access to patient education video library	Access to pre-installed educational videos	Same

7. Performance Data

Results from internal verification and validation testing 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 questions of safety and effectiveness were raised. The Care Team Portal was designed, verified, and validated according to the company's Design Control process. Testing included detailed functional, system level and usability testing. Test results demonstrated that the Care Team Portal meets all specifications and user needs.

The subject of this submission, Care Team Portal, did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing. Clinical studies were not required to demonstrate substantial equivalence of the Care Team Portal.

8. Conclusion

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