DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 14, 2017

Visicu Inc.
Milind Gramopadhye
Director of Quality and Regulatory
217 East Redwood St. Suite 1900
Baltimore, Maryland 21202

Re: K171029
Trade/Device Name: eCareCoordinator 1.5
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: June 15, 2017
Received: June 16, 2017

Dear Milind Gramopadhye:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171029

Device Name
eCareCoordinator 1.5

Indications for Use *(Describe)*

eCareCoordinator 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.

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
eCareCoordinator 1.5

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92(c).

Date Prepared: April 5, 2017

I. Submitter's name and address

Manufacturer: Visicu, Inc.
217 East Redwood Street
Suite 1900
Baltimore, MD 21202

Contact Person: Daniel R. Plonski
Senior Manager, Quality and Regulatory
Phone: 410-246-5357
Fax: 410-276-1970
E-mail: daniel.plonski@philips.com

II. Device information

Device Name: eCareCoordinator 1.5
Common Name: Telemedicine System
Classification panel: Cardiovascular

Classification	ProCode	Description
870.2910	DRG	Radiofrequency physiological signal transmitter and receiver.

III. Predicate device information

Trade name: eCareCoordinator
Manufacturer: Visicu, Inc.
510(k) clearance: K141706
Classification name Radiofrequency physiological signal transmitter and receiver.
Device class: Class II
Classification regulation: 21 CFR 892.2910
Classification panel: Cardiovascular
Product code: DRG

510(k) Summary

IV.Device Description

eCareCoordinator (eCC) is a software-only telemedicine system, designed to enable the support of patients in the home setting. eCC is intended to support the clinician with monitoring of remote patients. Clinicians use eCC to manage populations of ambulatory care patients, while keeping primary care physicians informed of patient status. eCC is a software-only device and does not contain any patient-contacting components.

V. Intended use/ Indications for Use

Intended Use:

eCareCoordinator is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCareCoordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.

Indication for Use:

eCareCoordinator 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.

VI.Comparison of Technological Characteristics with the Predicate Device

eCareCoordinator 1.5 is an enhanced version of eCareCoordinator 1.0, originally cleared under K141706.

A comparison matrix (Table 5-1) shows the similarities and differences. The eCareCoordinator 1.5 software with the listed enhancements is substantially equivalent to the previously cleared eCareCoordinator 1.0. The Intended Use has been modified to clarify and modernize the wording, however, the concept has not changed. Technological characteristics and principles of operation remain the same, Differences in the available features, as discussed below, do not present any new questions of safety or effectiveness.

510(k) Summary

Specification / Feature	eCareCoordinator 1.5 (Subject Device)	eCareCoordinator (Predicate device – K141706)	Comparison
Intended Use / Indications for Use / Target population			
Intended Use	eCareCoordinator is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCareCoordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.	eCareCoordinator is software intended for use in data aggregation, patient interaction facilitation, storage and clinical information management with independent physiological devices and ancillary systems that are connected either directly or through networks. The software is intended to provide patient information from the patient location through networking technology to a remote care team. eCareCoordinator does not send any real time alarms and is not intended to provide automated treatment decisions. This software is an informational tool only and is not to be used as a substitute for professional judgment of healthcare providers in diagnosing and treating patients.	Same
Indications for Use	eCareCoordinator 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.	eCareCoordinator and its accessories are indicated for use by patients and by care teams for managing patients who are capable and willing to engage in use of this software, to transmit medical and non-medical information through integrated technologies.	Same – wording updated for clarity.
Target population	At home patients	At home patients	Same
Technological Characteristics			
System components	Software Only	Software Only	Same
User Interfaces	Clinical (eCC) and Patient (eCP)	Clinical (eCC) and Patient (eCP)	Enhanced user interfaces
Clinician-Patient Communications	Two-way video	None	Added video communications
Measurement Features	None	None	Same

510(k) Summary

Specification / Feature	eCareCoordinator 1.5 (Subject Device)	eCareCoordinator (Predicate device – K141706)	Comparison
System Alarms	None	None	Same
Waveform Transmission	None	None	Same
User Access and Patient Data Security	User Authentication services, roles-based data access, logging for audit trail, locked down tablet	User Authentication services, roles-based data access, logging for audit trail, locked down tablet	Same
Clinical User Interface (eCC) Features			
Population View	Population screen with measurement and survey flags and other display fields	Population screen with measurement and survey flags and other display fields	Same
Overall Score	Sum of weighted scores for: Measurements, survey responses, issues, readmission risk and days since discharge	Sum of weighted scores for: Measurements, survey responses, issues, readmission risk and days since discharge	Same
Measurements View	Display of patient measurements and survey responses	Display of patient measurements and survey responses	Same
Patient Chart	Graphical and tabular displays of patient information	Graphical and tabular displays of patient information	Same
Intervention Rules	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
Surveys	Clinical users have option to send surveys to patients	Clinical users have option to send surveys to patients	Same
Protocols	Used to set patient tasks, surveys and intervention rules. Customizable by institution or clinician	Used to set patient tasks, surveys and intervention rules. Customizable by institution or clinician	Same
Clinician Tasks	Communication and tracking of clinical care tasks	Communication and tracking of clinical care tasks	Same
Sticky Notes	Optionally added to patient calendar	Optionally added to patient calendar	Same
Reports	Hard copy patient record report and system administration reports	System administration reports	Added patient record report
Patient User Interface (eCP) Features			
Platform	Android Tablet and legacy Telestation	Android Tablet and legacy Telestation	Same
Measurements from home devices	Wireless Bluetooth and manual entry	Manual entry	Bluetooth connectivity implemented
Appointments	Scheduled by care provider, appear on patient's	Scheduled by care provider, appear on patient's	Same

510(k) Summary

Specification / Feature	eCareCoordinator 1.5 (Subject Device)	eCareCoordinator (Predicate device – K141706)	Comparison
	calendar	calendar	
Activities and Reminders	Scheduled by care provider, appear on patient's calendar	Scheduled by care provider, appear on patient's calendar	Same
Surveys	Created and assigned to patients by the care provider	Created and assigned to patients by the care provider	Same
Video Calls	Capability to schedule and conduct video calls with care providers	None	Added video call capability
Educational Videos	Access to pre-installed educational videos	None	Educational videos added

Table 5-1 Comparison Table

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Summary of Non-clinical testing

No performance standards for telehealth systems or components have been issued under the authority of Section 514. eCareCoordinator was tested in accordance with Philips verification and validation processes. Quality Assurance measures were applied to the system design and development, including:

- Risk Analysis
- Product Specifications
- Design Reviews
- Verification & Validations

Summary of Clinical Testing

Clinical Performance testing for Philips eCareCoordinator 1.5 was not performed, as there were no new clinical applications that had hazards or risk mitigations that required clinical performance testing to support equivalence.

Conclusions drawn from the Non-clinical and Clinical testing

Verification validation activities have been conducted to establish the performance, functionality, and usability characteristics of the new device with respect to the predicate, intended use and defined requirements. Testing included detailed functional, system level and usability testing. Test results demonstrated that eCareCoordinator 1.5 meets all specifications and user needs.

VIII. Conclusion

eCareCoordinator 1.5 is substantially equivalent to the previously cleared eCareCoordinator. Both devices have the same intended use, indications for use, technological characteristics and principles of operation. Differences in the available features, as discussed above, do not change the intended use or present any new questions of safety or effectiveness.