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

August 3, 2017

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

Re: K171322
Trade/Device Name: eCareManager 4.1
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: May 5, 2017
Received: May 5, 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)*
K171322

Device Name
eCareManager 4.1

Indications for Use *(Describe)*

Intended Use Statement:
The eCareManager System is a software tool intended for use by trained medical staff providing supplemental remote support to bedside care teams in the management and care of in-hospital patients. The software collects, stores and displays clinical data obtained from the electronic medical record, patient monitoring systems and ancillary systems connected through networks. Using this data, clinical decision support notifications are generated that aid in understanding the patient's current condition and changes over time. The eCareManager System does not provide any alarms. It is not intended to replace bedside vital signs alarms or proactive patient care from clinicians.

All information and notifications provided by the eCareManager System are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making.

Indications for Use Statement:
The eCareManager software is indicated for use in hospital environment or remote locations with clinical professionals. It is not indicated for home use.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
eCareManager 4.1

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

Date Prepared: May 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:	eCareManager 4.1
Manufacturer:	Visicu, Inc.
Common Name:	Telehealth Software
Classification name	System, network and communication, physiological monitors
Device class:	Class II
Classification regulation:	21 CFR 870.2300
Classification panel:	Cardiovascular
Product Code:	MSX

III. Predicate device information

Device Name:	eCareManager 4.0 (K153156)
Manufacturer:	Visicu, Inc.
Common Name:	Telehealth Software
Classification name	System, network and communication, physiological monitors
Device class:	Class II
Classification regulation:	21 CFR 870.2300
Classification panel:	Cardiovascular
Product Code:	MSX

510(k) Summary

Device Description

The eCareManager system is a software platform that enables enterprise telehealth. The system includes interface features to acquire patient data from the electronic medical record and bedside devices which can be shared between the bedside and remote care teams. Population management and communication features facilitate a collaborative approach to delivery of in-patient care. The system's clinical decision support features further aid in the proactive delivery of care. Using data received from the hospital's systems, clinical decision support algorithms provide cues that assist in the early detection of changes in patient condition.

IV.Intended use/ Indications for Use

Intended Use:

The eCareManager System is a software tool intended for use by trained medical staff providing supplemental remote support to bedside care teams in the management and care of in-hospital patients. The software collects, stores and displays clinical data obtained from the electronic medical record, patient monitoring systems and ancillary systems connected through networks. Using this data, clinical decision support notifications are generated that aid in understanding the patient's current condition and changes over time. The eCareManager System does not provide any alarms. It is not intended to replace bedside vital signs alarms or proactive patient care from clinicians.
All information and notifications provided by the eCareManager System are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making.

Indication for Use:

The eCareManager software is indicated for use in hospital environment or remote locations with clinical professionals. It is not indicated for home use.

V. Comparison of Technological Characteristics with the Predicate Device

eCareManager 4.1 is an enhanced version of our previously cleared eCareManager 4.0 software product (K153156). While the intended use and technological characteristics remain the same, eCareManager 4.1 provides enhanced patient administration and clinical decision support features. Differences in the available features, summarized in table 5.1 below, do not present any new questions of safety or effectiveness.

510(k) Summary

Table 5-1 Comparison Table

Specification / Feature	eCareManager 4.1 (Subject Device)	eCareManager 4.0 (Predicate device) K153156	Comparison
Intended Use / Indications for Use / Target population			
Intended Use	The eCareManager System is a software tool intended for use by trained medical staff providing supplemental remote support to bedside care teams in the management and care of in-hospital patients. The software collects, stores and displays clinical data obtained from the electronic medical record, patient monitoring systems and ancillary systems connected through networks. Using this data, clinical decision support notifications are generated that aid in understanding the patient's current condition and changes over time. The eCareManager System does not provide any alarms. It is not intended to replace bedside vital signs alarms or proactive patient care from clinicians. All information and notifications provided by the eCareManager System are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making.	The eCareManager System is a software tool intended for use by trained medical staff providing supplemental remote support to bedside care teams in the management and care of in-hospital patients. The software collects, stores and displays clinical data obtained from the electronic medical record, patient monitoring systems and ancillary systems connected through networks. Using this data, clinical decision support notifications are generated that aid in understanding the patient's current condition and changes over time. The eCareManager System does not provide any alarms. It is not intended to replace bedside vital signs alarms or proactive patient care from clinicians. All information and notifications provided by the eCareManager System are intended to support the judgement of a medical professional and are not intended to be the sole source of information for decision making.	Same
Indications for Use	The eCareManager software is indicated for use in hospital environment or remote locations with clinical professionals. It is not indicated for home use.	The eCareManager software is indicated for use in hospital environment or remote locations with clinical professionals. It is not indicated for home use	Same
Target population	In-hospital patients	In-hospital patients	Same
Technological Characteristics			
System components	Software Only	Software Only	Same

510(k) Summary

Specification / Feature	eCareManager 4.1 (Subject Device)	eCareManager 4.0 (Predicate device) K153156	Comparison
Interfaces to hospital systems	HL-7	HL-7	Same
Bedside to Remote Communications	Audio/Video	Audio/Video	Same
Measurement Features	None	None	Same
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	User Authentication services, roles-based data access, logging for audit trail	Same
Patient Administration Features			
Patient Census	Patient Census screen with status indicators	Patient Census screen with status indicators	Enhanced display
Graphical Census	Graphical display of patient status	Graphical display of patient status	Enhanced display
Patient Profile	Summary of patient information including diagnosis, treatments, best practices and trends	Summary of patient information including diagnosis, treatments, best practices and trends	Same
Stroke Profile	Summary of clinical data and workflow time tracking	Summary of clinical data and workflow time tracking	Same
Care Plan	Summary of clinical care plan and therapeutic objectives	Summary of clinical care plan and therapeutic objectives	Same
Task List	Communication and tracking of clinical care tasks	Communication and tracking of clinical care tasks	Same
Flowsheets	Electronic charting of vital signs and infusions, intake and output, nursing assessments and care, respiratory therapy, and lines, tubes and drains	Electronic charting of vital signs and infusions, intake and output, nursing assessments and care, respiratory therapy, and lines, tubes and drains	Same
Order Entry	Medication and non-medication orders. Drug interaction and allergy screening	Medication and non-medication orders. Drug interaction and allergy screening	Same
Patient Notes	Supports entry of patient notes with configurable templates	Supports entry of patient notes with configurable templates	Same
Program Forms	Configurable data entry forms for tracking clinical program performance, based on customer initiatives	Configurable data entry forms for tracking clinical program performance, based on customer initiatives	Same
Reports	Operational, Clinical Care and Billing reports provided	Operational, Clinical Care and Billing reports provided	Same

PHILIPS

eCareManager 4.1
Traditional 510(k)

510(k) Summary

Specification / Feature	eCareManager 4.1 (Subject Device)	eCareManager 4.0 (Predicate device) K153156	Comparison
Clinical Decision Support Features			
Automated Acuity Score	Provides a relative scoring of patient condition	Provides a relative scoring of patient condition	Modified parameters, to include lab values and modified graphical presentation
Pain, Agitation and Delirium	Graphical summary of PAD related issues	Graphical summary of PAD related issues	Modified graphical presentation
Discharge Readiness Score	Objective measurement of risk of death or readmission	Objective measurement of risk of death or readmission	Same
Early Warning Score	Graphical summary of physiological changes	Graphical summary of physiological changes	Modified graphical presentation and scoring range
Vital Signs Monitoring	Retrospective	Retrospective	Same
Laboratory Results	Received via hospital system interface or manual entry	Received via hospital system interface or manual entry	Same
Smart Alerts	Visual cues based on automated assessment of patient data. Patient specific configuration	Visual cues based on automated assessment of patient data. Patient specific configuration	Same

VI.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. eCareManager 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

Changes to the Automated Acuity Score calculation have been validated using clinical data collected under an observational, non-human subject evaluation. The evaluation demonstrated substantial equivalence of the modified calculation with the unmodified, predicate device version.

510(k) Summary

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 eCareManager software release 4.1 meets all device specifications and user needs.

VII. Conclusion

eCareManager 4.1 is substantially equivalent to the predicate eCareManager 4.0 (K153156) in terms of design features, fundamental scientific technology, intended use, safety and effectiveness. Substantial equivalence has been demonstrated with non-clinical performance testing and validation using clinical datra. The verification and validation results provided in this 510(k) premarket notification demonstrate that the subject device, CareManager 4.1, is as safe and effective as the predicate device without raising any new safety and/or effectiveness concerns.