June 3, 2022

Visicu, Inc.
Janine Treter
Regulatory Affairs Specialist
217 East Redwood Street
Baltimore, Maryland 21202

Re: K211046
Trade/Device Name: eCareManager 4.5
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: May 4, 2022
Received: May 6, 2022

Dear Janine Treter:

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

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.

510(k) Number *(if known)*
K211046

Device Name
eCareManager 4.5

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 solely 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.

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"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

510(k) Summary	
I. SUBMITTER	
Date Prepared	03-June-2022
Submitter/Owner	Visicu, Inc. Site Number: 1125873 217 East Redwood St. Suite 1900 Baltimore, MD 21202 Business Trade Names: (1) Philips (2) Philips Visicu Inc.
Key Contact	Janine Treter Regulatory Affairs Manager janine.treter@philips.com
510(k) Submission Type	Traditional 510(k)
II. DEVICE	
Trade Name	eCareManager 4.5
Common Name	Telehealth Software
Classification Name	Class II Part 870 Cardiovascular Subpart C Cardiovascular Monitoring Devices Sec. 870.2300 Cardiac monitor (including cardiotachometer and rate alarm). Product Code: MSX Description: System, Network and Communication, Physiological Monitors

III. PREDICATE DEVICE			
Predicate Device	***510(k) No.***	***Company Name*** ***Device Name***	***Product Code***
	K171322	Visicu, Inc. eCareManager 4.1	MSX
The eCareManager 4.5 is substantially equivalent in intended use and technological characteristics to the eCareManager 4.1 (K171322).			

IV. DEVICE DESCRIPTION

eCareManager 4.5 – description of the device per 21 CFR 807.92(a) (4)

The eCareManager System is a collection of software applications designed to facilitate the delivery of high-quality critical care services with the assistance of a Telehealth Center Program (THC). The THC provides an organizational and technology platform to transform critical care by redesigning the way critical care is structured and managed. The THC Care Team is a multi-professional team that includes both bedside and THC remote clinicians working together to ensure the best care is provided. The eCareManager System provides a robust toolset that helps ICU and Acute Care clinicians plan, document, and standardize care around best practices.

Population management and communication applications facilitate a collaborative approach to delivery of in-patient care. The system's clinical decision support applications 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.

V. INDICATIONS FOR USE

Intended Use as required per 21 CFR 807.92(a)(5)

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.

Indications for Use

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

Comparison of Intended Uses for Subject Device and Predicate

Name	**Indications for Use/Intended Use**
Subject Device eCareManager 4.5	**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. **Indications for Use** The eCareManager software is solely indicated for use in hospital environment or remote locations with clinical professionals. It is not indicated for home use
Predicate Device K171322 - eCareManager 4.1	The Intended Use is the same of the predicate device. The indication for use statement is equivalent to the predicate device. the word "solely" was added to give emphasis to the exclusive use which is in-hospital patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE	
Similarities	
Item of Comparison	**Description/Rationale**
Technological Characteristics	
System components	Software as a medical device (SaMD)
Interfaces to hospital systems	HL-7
Bedside to Remote Communications (bilateral exchange)	Patient sign-out tool for written communication/ task assignment Audio/Video – Vidyo, Proconnections
Measurement Features	None
System Alarms	None
Waveform Transmission	None
Deployment	On premise
Population Health Applications	
Graphical Census	Graphical display of patient status
Patient Profile	Summary of key clinical data regarding patient information including diagnosis, treatments, best practices and trends
Watchlist	Graphical display of patient status based on clinical decision support tools; companion tool of the Graphical Census
Patient Administration	Provides Admit, Discharge and Transfer (ADT) functions for management of patient flow. Received via hospital system interface or manual entry
Care Plan	Summary of clinical care plan and therapeutic objectives
Task List	Communication and tracking of clinical care tasks

Quick Entry	Alternative data entry form for documenting patient clinical status to clinical decision support functionalities.
External Links	Allows the user to access external websites from a Patient Chart (PACs imaging studies, microbiology results, etc)
Lines, Tubes, and Drains (LTD)	Allows clinicians to document and manage various types of lines, tubes, and drains used for treating patients
Active Diagnoses & Treatment (Dx/Rx)	Allows clinicians to enter active diagnoses and treatments without having to create a note
Patient Registry	Alternative data display and edition capabilities outside of the main application areas.
eLerts and Notifications	Displays eLert messages and Task reminders for clinical users.
Patient Notes	Supports entry of patient notes with configurable templates
Flowsheets	Electronic charting of vital signs and infusions, intake and output, nursing assessments and care, respiratory therapy
Labs and Radiology	Results received via hospital system interface or manual entry
Microbiology	Displays patient microbiology information received via hospital system interface or manual entry
Reports	Operational, Clinical Care and Billing reports provided
Clinical Decision Support Applications	
Automated Acuity Score	Provides a relative scoring of patient condition – improving or worsening data for rapid identification and assessment
Pain, Agitation and Delirium	Graphical summary of PAD related issues
Early Warning Score	Graphical summary of physiological changes to identify signs of early deterioration
Discharge Readiness Score	Objective measurement of risk of death or readmission within 48 hours from discharge

Order & Medications	Enables physicians to create orders that screen medications for drug interactions and patient allergies
Telestroke	Consultative care module in evaluating patients with suspected stroke and care management through tasks, timing, and workflow activities.
Differences	
Indications for Use	
The Indication for use statement is equivalent to the predicate device. The word "solely" was added to give emphasis to the exclusive use.	
Technological Characteristics	
Bedside to Remote Communications (bilateral exchange)	Audio/Video – Addition of Univago HE as another optional third-party video solution. It is equivalent to existing third-party solutions. Compatibility testing was performed and no unanticipated issues in performance resulted from the verification.
User Access and Patient Data Security	User Authentication services, roles-based data access, logging for audit trail are equivalent to the predicate device containing additional cybersecurity features including improved auditing capabilities, FIPS compliant encryption, and compliance with the Department of Defense (DoD) Risk Management Framework (RMF).
Deployment	Hosted beyond on premise deployment. The code and server deployment structure in the hosted environment is the same to the on premise environment. Successful essential performance testing was performed in the hosted and on premise environment. No unanticipated issues in performance resulted from validation.
Population Health Applications	
Patient Census	Patient Census screen with status indicators for management as a population with cosmetic enhancement for identification of when a video session is in progress and addition of a column. No new risks of safety and efficacy were identified.
Ventilation Patient Census	New application which is a consolidated view of patients receiving invasive mechanical ventilation for management as a population. Same data source from respiratory flowsheet. Software verification and validation of the

	change did not result in any unintended changes to the software or unexpected results. No new risks of safety and efficacy were identified.
Vital Signs	Displays near real-time vital sign data, including the last 15 minutes of vital signs at 1-minute intervals, and historical vital sign data (over the last 24 hours). An additional Inbound Field was included following the principles of other existing Inbound Fields.
Program Form	Configurable data entry forms for tracking clinical program performance, based on customer initiatives. New form option was included to allow remote clinicians to document specific clinical interventions.
Clinical Decision Support	
Spontaneous Awakening Trials or Spontaneous Breathing Trial (SAT/SBT)	Visual cues for patients which fits the established criteria for early identification of patients ready to SAT/SBT. New application using same data source from respiratory flowsheet. SAT/SBT screen was utilized as a performance and preferential benchmark with users. Display of information following the same principles of other existing CDS applications.
APACHE Admission Diagnosis	Provides retrospective scoring on severity-of-disease classification to compare populations of patients. A consolidated view of patient APACHE day in one screen highlighting missing data was added. Bench verification supporting the change.
Smart Alerts	Visual cues based on automated assessment of patient data displayed according to a set of pre-defined events. Patient specific configuration. Sentry Alerts have been enhanced to allow default settings at the unit level and introduce a more intuitive user interface to allow for configuration. Previously these default settings were set for the entire population or could be customized at an individual level. Users can still keep the default settings or change if individual patient condition warrants the change. Permissions for alert settings remain unchanged.
Sepsis Prompt	Visual cue based on automated assessment of abnormalities as per inflammation signs. Philips Sepsis Prompt has been updated to align with the new sepsis definition established Third International Consensus Conference.

Substantial Equivalence Summary

Operational and technological characteristics form the basis for the determination of substantial equivalence of the eCareManager 4.5 with the legally marketed predicate devices (K171322). The eCareManager 4.5 is substantially equivalent to the predicate devices.

VII. PERFORMANCE DATA

Non-Clinical Testing

No performance standards for telehealth software 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 Device Hazard Analysis; Product Specifications; Design Change Controls and Maintenance; Verification and Validations; and Cybersecurity Risk Assessment and Testing.

Verification and validation activities have been conducted to establish the performance, functionality, and usability characteristics of the enhanced eCareManager version with respect to the predicate, intended use and defined requirements. Verification testing included Unit Testing, Integration Testing and System Level Testing (Functional and Regression Testing, Integration Testing, Migration Testing, Localization Testing, Performance/Load Testing and Compatibility Testing). Validation testing included the following System Level Testing: User/Commercial Requirements Validation, Essential Performance Testing and Human Factors/Usability Testing.

Software verification and validation tests were successfully executed on the eCareManager. The testing suite included functional and non-functional testing including security and load testing. All predetermined acceptance criteria were met, demonstrating that the device performs appropriately per defined specifications, and correctly incorporates all required safety mitigations. Results of the software verification and validation testing suite demonstrate substantial equivalence to the predicate system.

VIII. CONCLUSION

eCareManager 4.5 was established as a Multiple Function device product based on the Agency current thinking, where two applications were identified as the device functions under review which are Automated Acuity and Discharge Readiness Score.

The results of the substantial equivalence assessment, taken together with non-clinical bench testing, software verification and validation demonstrate that the eCareManager 4.5 does not raise different questions of safety and effectiveness when compared to the predicate, performs as intended, and has performance characteristics that are substantially equivalent to the eCareManager 4.1 predicate device.