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

September 30, 2016

Visicu, Inc.
Daniel Plonski
Manager, Quality and Regulatory
217 East Redwood Street, Ste. 1900
Baltimore, Maryland 21202

Re: K153156
Trade/Device Name: eCareManager 4.0.1
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, PLB, OUG, NSX
Dated: September 19, 2016
Received: September 19, 2016

Dear Daniel Plonski:

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 yours,

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)*
K153156

Device Name
eCareManager 4.0.1

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.

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510(k) Summary
eCareManager 4.0.1

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

Date Prepared: September 22, 2016

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
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II. Device information

Device Name: eCareManager 4.0.1
Common Name: Telehealth Software
Classification panel: Cardiovascular

Classification	ProCode	Description
870.2300, II	PLB	Multivariate Vital Signs Index
870.2450, Enf. Dis.	NSX	Software, Transmission and Storage, Patient Data
870.2300, II	MSX	System, Network and Communication, Physiological Monitors
880.6310, I	OUG	Medical Device Data System

III. Predicate device information

Trade name: Argus System
Manufacturer: Visicu, Inc.
510(k) clearance: K012171
Classification name System, network and communication, physiological monitors
Device class: Class II
Classification regulation: 21 CFR 892.2300
Classification panel: Cardiovascular
Product code: MSX

510(k) Summary

Trade name:	Philips IntelliVue Patient Monitors
Manufacturer:	Philips Medizin Systeme Boeblingen Gmbh
510(k) clearance:	K113657
Classification name	Patient Physiological Monitor (with arrhythmia detection or
alarms)Device class:	Class II
Classification regulation:	21 CFR 892.2300
Classification panel:	Cardiovascular
	Product code: MHX, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DRT, DPS, MLC, DRW, KRC, DRJ, DQA, DSB, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LKD, KLK, KOI, GWR, GWS, FLL

IV. Device Description

The eCareManager (eCM) system is a software platform that enables enterprise telehealth. The system includes an interface to acquire patient data from the electronic medical record and bedside devices. eCM provides a history of the patient population in clinic and provides a clinical decision support feature to aid in the proactive delivery of consultative care for the patient

V. 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.

VI.Comparison of Technological Characteristics with the Predicate Device

The eCareManager software is Telehealth software, which employs and further builds on the same fundamental scientific technology as the Argus System software (K012171). The Sepsis Screening Prompt included in eCareManager has the same intended use and technological characteristics as the sepsis screening feature (Protocol Watch SSC) marketed with several models of the Philips IntelliVue Patient Monitors (K113657).

A comparison matrix (Table 5-1) shows the similarities and differences. The eCareManager software with the listed enhancements is substantially equivalent to the previously cleared Argus System. 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. Table 5-2 presents a comparative summary of the sepsis screening features of eCareManager and the IntelliVue Patient Monitors with ProtocolWatch SSC.

Table 5-1 Comparison Table (eCareManager/Argus System)

Specification / Feature	eCareManager (Subject Device)	Argus System (Predicate device - K012171)	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.	The Argus System – Continuous Expert Care Network (CXCN) with Smart Alarms enhancement is for use in data collection, storage and clinical information management with independent bedside devices, and ancillary systems that are connected either directly or through networks. It is also intended to provide patient information and surveillance of monitored patients at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated telephone lines.	Same intent, however, language modified to clarify the following with regard to eCareManager: • Intended for use by trained medical staff • Intended for supplemental support of bedside care team • Does not provide any alarms • Does not replace bedside vital sign alarms • Does not replace proactive clinical care • Supports medical judgement, does not replace it • Not intended to be sole source of information for decision making.

510(k) Summary

Specification / Feature	eCareManager (Subject Device)	Argus System (Predicate device - K012171)	Comparison
	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 indicated for use in hospital environment or remote locations with clinical professionals. It is not indicated for home use.	The Argus System is intended to provide patient information and surveillance of monitored patients at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated telephone lines.	Same but with eCareManager emphasis on not for home use.
Target population	In-hospital patients	In-hospital patients	Same
Technological Characteristics			
System components	Software Only	Software Only	Same
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	Same
Graphical Census	Graphical display of patient status	None	Provides visual representation of patient status
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 but modifications to screen layout
Stroke Profile	Summary of clinical data and workflow time tracking	None	Summary of patient data based on NIHSS guidelines

510(k) Summary

Specification / Feature	eCareManager (Subject Device)	Argus System (Predicate device - K012171)	Comparison
Care Plan	Summary of clinical care plan and therapeutic objectives	Summary of clinical care plan and therapeutic objectives	Same but modifications to screen layout
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 but modifications to screen layout
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	None	New administrative feature
Reports	Operational, Clinical Care and Billing reports provided	Operational, Clinical Care and Billing reports provided	Expanded list of preconfigured reports
Clinical Decision Support Features			
Vital Signs Monitoring	Retrospective data display.	Near-real time	Technology is the same however, “Retrospective data display” is more accurate than previously used “near-real-time”
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	Technical differences in computation methods have been validated to demonstrate no negative effects on safety and effectiveness

510(k) Summary

Table 5-2 Comparison Table (eCareManager/IntelliVue ProtocolWatch SSC)

Specification / Feature	eCareManager (Subject Device)	IntelliVue w/ProtocolWatch SSC (K113657)	Comparison
Intended Use / Indications for Use / Target Population (for the overall device/software application)			
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 monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment. The MX500/MX550 monitors are additionally intended for use in transport situations within hospital environments. The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.	**Similarities:** Both devices are intended for use by medical professionals in a hospital environment. Both devices collect and record data for patient monitoring. Both devices provide clinical decision support tools (including sepsis screening). Neither device is intended to provide any diagnosis or treatment. Both devices are for prescription use only. Neither device is intended for home use. **Differences:** eCareManager does not provide any alarms. eCareManager is not indicated for paediatrics or neonates. eCareManager is not indicated for use in transport situations. eCareManager is intended to provide information to remote clinicians. IntelliVue is intended to provide information to bedside clinicians.
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 SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.	Both devices provide sepsis screening features intended for adult patients.

Specification / Feature	eCareManager (Subject Device)	IntelliVue w/ProtocolWatch SSC (K113657)	Comparison
Target population	In-hospital patients	In-hospital patients (Sepsis features only for adults)	Same
Technological Characteristics (for the sepsis screening function)			
Screening Purpose	The eCare Manager Sepsis Screening Prompt monitors patients at risk for sepsis. By automating sepsis monitoring for patients, the feature can help clinical teams detect early signs of sepsis, so they can begin assessment and treatment plans quickly.	The intention of the Severe Sepsis Screening is to provide clinicians with the "link" between the signs and symptoms of the patient and the possibility of sepsis development. Once this is achieved, the clinician is prompted to seek authorized clinician review.	Same: Both applications are designed to assist clinicians in recognizing the early signs and symptoms of sepsis and proactively getting the patient the appropriate level of care at an early stage. Both systems recommend human follow-up for sepsis assessment.
Sepsis Screening Criteria	• Temperature • Heart Rate • Respiratory Rate • White Blood Cell Count/Bands • Mental Status • Serum Glucose • Ileus • INR • Lactate	• Temperature • Heart Rate • Respiratory Rate • White Blood Cell Count • Mental Status • Hyperglycemia • Chills with rigors	eCareManager automatically assesses 9 criteria from the 2003 international consensus conference for screening. Intelliview automatically assesses 3 criteria from the 1992 consensus conference and has the clinician asses the remaining items manually. The eCareManager sepsis screening model, yielded higher discrimination for identifying severe sepsis than traditional criteria as used in the Intellivue SSC model.
Basis of Criteria	2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. Crit Care Med 2003 Vol 31, No.4	2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. Crit Care Med 2003 Vol 31, No.4	Same

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. 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

Clinical validation for the Philips eCareManager software release 4.0.1 included both model development and post-implementation studies to evaluate the performance of the Sepsis Screening Prompt algorithm.

Conclusions drawn from the Non-clinical and Clinical testing

Verification and 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, usability and clinical performance testing. Test results demonstrate that eCareManager software release 4.0.1 meets all device specifications and user needs.

VIII. Conclusion

eCareManager is substantially equivalent to the predicate device Argus System (K012171) in terms of design features, fundamental scientific technology, intended use, safety and effectiveness. Differences in computational methods, as noted above, do not alter the intended use nor do they present any new questions of safety and effectiveness. Substantial equivalence was demonstrated with non-clinical and clinical performance testing, which complied with the requirements specified in the international and FDA-recognized consensus standards.

The non-clinical and clinical performance tests provided in this 510(k) premarket notification demonstrate that the subject device, eCareManager, is as safe and effective as the predicate device without raising any new safety and/or effectiveness concerns.

The Sepsis Screening Prompt included in eCareManager is substantially equivalent to the IntelliVue Protocol Watch SSC. Based on eCareManager's intended use to provide supplemental remote support to bedside care teams, eCareManager is as safe as the Intellivue device and clinical validation demonstrates adequate performance for its intended use.