DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 9, 2016

AMC Health
Jonathan Shankman
Sr. VP, Clinical Innovation
39 Broadway, Suite 540
New York, New York 10006

Re: K151839
Trade/Device Name: AMC Health VitalCaregiving System II
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: July 1, 2015
Received: July 6, 2015

Dear Jonathan Shankman:

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.

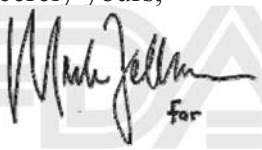
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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)*
K151839

Device Name
AMC Health VitalCaregiving System II

Indications for Use *(Describe)*
The AMC Health VitalCaregiving System II ("VitalCaregiving System II") is intended to be used in conjunction with biometric measuring devices, mobile applications and questionnaires to collect and store data, and for clinician scheduled monitoring at home and in non-acute medical facilities. The VitalCaregiving System II securely sends data from a patient monitoring device to a central electronic log of patient information, from which notifications/alerts and reports can be generated and data can be securely viewed by authorized caregivers and patients. Clinicians would then determine how and when to respond to the alerts/notifications and biometric data. For use by adults 18 years and older who do not have an acute care or emergency health care condition.

• Data can be sent via intranet networks, the internet, landline and cellular telephones and other mobile devices.
• The software also supports communication between patients and caregivers or researchers, such as bidirectional audio and video e-visits, telephone and mobile text messaging.

The VitalCaregiving System II is not intended for use in emergency situations or by a patient in an acute care medical facility and is not for active patient monitoring.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

Prepared September 8, 2016

Submitted by: Jonathan Shankman

Contact Person: Jonathan Shankman
Telephone: 212-422-3037
Email: jshankman@amchealth.com
Product Name: AMC Health VitalCaregiving System II

Common Name: Patient Monitoring System

Classification: Cardiovascular, MWI, 21 CFR 870.2300; DXH, 21 CFR 870.2920

Predicate Device: Advanced Monitored Caregiving VitalCaregiving System and AirStrip Remote Patient Monitoring

Intended Use:
The AMC Health VitalCaregiving System II is a software-only device used alongside vital signs monitoring devices for data storage, collection and transmission.

Indications for Use:
The AMC Health VitalCaregiving System II ("VitalCaregiving System II") is intended to be used in conjunction with biometric measuring devices, mobile applications and questionnaires to collect and store data, and for clinician scheduled monitoring at home and in non-acute medical facilities. The VitalCaregiving System II securely sends data from a patient monitoring device to a central electronic log of patient information, from which notifications/alerts and reports can be generated and data can be securely viewed by authorized caregivers and patients. Clinicians would then determine how and when to respond to the alerts/notifications and biometric data. For use by adults 18 years and older who do not have an acute care or emergency health care condition.

- Data can be sent via intranet networks, the internet, landline and cellular telephones and other mobile devices.
- The software also supports communication between patients and caregivers or researchers, such as bidirectional audio and video e-visits, telephone and mobile text messaging.

The VitalCaregiving System II is not intended for use in emergency situations or by a

patient in an acute care medical facility and is not for active patient monitoring.

Device Description:

The AMC Health VitalCaregiving System II ("VitalCaregiving System II") is a software only device. VitalCaregiving System II enables clinicians and patients to conduct bidirectional audio-video conversations and collects patient-reported outcomes and self-care activities via assessment questionnaires. Biometric measurements using third party devices can be taken by the patient while being observed over videoconference by a clinician who is located remotely, or measurements can be made by the patient at any time, without being observed by a clinician. Clinicians can also use VitalCaregiving System II to exchange messages with patients by text or telephone.

The system is indicated when health professionals wish to directly interact with patients via video, voice and/or text, and/or view reports of medical parameters collected from patients with non-acute conditions using remote biometric measuring devices and questionnaires. The AMC system is not intended for use in emergency situations.

Comparison with Predicate Devices:

The submission device and the predicate device have substantially equivalent intended use and technological specifications.

COMPARISON TABLE

The following table provides a comparison of indications for use, technological characteristics, and functionality.

	Predicate Device: Advanced Monitored Caregiving VitalCaregiving System I	Predicate Device: AirStrip RPM Epiphany Adapter	Subject Device: AMC Health VitalCaregiving System II
510(k) Number	**K051544**	**K133450**	
FDA Classification	Transmitters And Receivers, Electrocardiograph, Telephone	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	Transmitters And Receivers, Electrocardiograph, Telephone; Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Classification Code	DXH	MWI	MWI; DXH
Regulation Number	870.2920	870.2300	870.2300; 870.2920
Intended Use	The Advanced Monitored Care ("AMC") System is intended to be used in conjunction with home patient measuring devices to send	AirStrip RPM is software capable of displaying physiologic and other patient information. This	AMC Health VitalCaregiving System II is a software-only device used alongside vital signs

	the measured parameters from a patient's home to a central computer via an intermediary organization, where reports can be generated for the physician and data can be reviewed over the Internet by physicians and patients.	information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians. AirStrip RPM is intended to be used by clinicians for the following purposes: 1. By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital; 2. To view the near real-time waveforms remotely; 3. To remotely review other standard or critical near real-time patient data from the monitored system; To provide a request for remote consultation regarding a patient's waveform or other data.	monitoring devices for data storage, collection and transmission.
Indication for Use	The Advanced Monitored Care ("AMC") System is intended to be used in conjunction with home patient measuring devices to send the measured parameters from a patient's home to a central computer via an intermediary organization, where reports can be generated for the physician and data can be reviewed over the Internet by physicians and patients.	AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians. AirStrip RPM is intended to be used by clinicians for the following purposes: 4. By using a cellular	The AMC Health VitalCaregiving System II ("VitalCaregiving System II") is intended to be used in conjunction with biometric measuring devices, mobile applications and questionnaires to collect and store data, and for clinician scheduled monitoring at home and in non-

		telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital; 5. To view the near real-time waveforms remotely; 6. To remotely review other standard or critical near real-time patient data from the monitored system; 7. To provide a request for remote consultation regarding a patient's waveform or other data.	acute medical facilities. The VitalCaregiving System II securely sends data from a patient monitoring device to a central electronic log of patient information, from which notifications/alerts and reports can be generated and data can be securely viewed by authorized caregivers and patients. Clinicians would then determine how and when to respond to the alerts/notifications and biometric data. For use by adults 18 years and older who do not have an acute care or emergency health care condition. • Data can be sent via intranet networks, the internet, landline and cellular telephones and other mobile devices. • The software also supports communication between patients and caregivers or researchers, such as bidirectional audio and video e-visits, telephone and mobile text messaging.

			The VitalCaregiving System II is not intended for use in emergency situations or by a patient in an acute care medical facility and is not for active patient monitoring.
Intended Users	Patients and physicians	Clinicians, when they cannot be at the hospital	Caregivers and patients at home or in a non-acute care medical facility, and by physicians who wish to monitor and interact with patients remotely
Available over the counter	No	No	No
Standard 60601-2-47 Medical Electrical Equipment	N/A	N/A	"This standard does not apply to systems that do not continuously record and analyze the ECG (for example, 'intermittent event recorders')." The VitalCaregiving System II does not continuously record and analyze ECG.
Standard EC53 ECG Trunk Cables and Patient Leadwires	N/A	N/A	The VitalCaregiving System II does not use any ECG trunk cables or Patient lead wires. There is no electrical connection to the patient.
Standard 11073-10406 Health Informatics	N/A	N/A	The VitalCaregiving System II is not a basic 1- to 3-lead ECG.
Clinicians, researchers, care coordinators, patients and their informal caregiver(s) can securely access the information hub and/or mobile application via the Internet by using a unique	Yes	Yes	Clinicians, researchers, care coordinators, patients and their informal caregiver(s) can securely access the information hub and/or mobile application via the Internet by using a unique username and strong password

username and strong password			
Data Acquisition: Medical device data is obtained from a patient's device through several potential gateways, such as the wired or wireless modem, a mobile phone or tablet, a cellular-enabled medical device or a partner service application.	Yes	Yes	Yes, and in addition, AMC has established pathways for each gateway to extract data from the medical device and input it into AMC's cloud-based data center.
Data Transmission: medical device data is securely transferred via Internet between providers and the hub.	Yes	Yes	Yes, in addition, AMC used an encrypted transport technology with redundant, private connections between the network providers and AMC's cloud-based data center.
Data Storage/Access: Securely stores and manages encrypted patient measurements medical device data is available through the interface of choice for the patient, physicians, or other partners to securely access the patient's information.	Yes	Yes	Yes, in addition, after the AMC Platform has received the transmission, the patient's information is available in a number of tabular and graphical views, providing a detailed analysis of the data. The patient's caregiver(s) utilize these analyses to evaluate the patient's health status.
Patient Engagement: The system facilitates interactive patient engagement via several potential gateways, such as secure messaging,	Yes	Yes	Yes, in addition AMC provides for interactive eVisits between patient/ caregiver and clinician. Generates alerts, notifications, reports and dashboards for patients and authorized caregivers. Patients and caregivers can both enter

interactive voice and video response (IVVR).			information into the patient record via mobile and web user interfaces. All user interactions are logged with rich meta-data audit.
Data Integration	Yes	Yes	Yes: On a scheduled or near real-time basis, the system securely transfers patient information to 3rd party applications, such as electronic health records (EHR), personal health records (PHR) and electronic data capture (EDC)

The VitalCaregiving System II is compatible with the Samsung Note 2 and Samsung Note 3 for the following functions: eVisit; eMessage; and Mobile Surveys.

The VitalCaregiving System II is compatible with the Samsung Note 2 for the collection of biometric data with the following third-party devices:

1. **A&D 351-PBT-ci Weight scale**

2. **Choicemed MD300C318T2 Pulse Oximeter**

The VitalCaregiving System II cannot be used to collect biometric data with the Samsung Note 3.

Third Party Measurement Devices (reference devices)		
The Subject Device has been Tested with the Following Third-Party Devices:	**Physiological Measurements Obtained and Verified by Subject Device from Third-Party Device**	**Non-Physiological Measurements Obtained by Subject Device from Third-Party Device**
1. A&D UA-851PBT	Systolic pressure; diastolic pressure; pulse rate	
2. A&D UA-767	Systolic pressure; diastolic pressure; pulse rate	

3. A&D UA-851PBT	Systolic pressure; diastolic pressure; pulse rate	
4. A&D UA-767PBT-Ci	Systolic pressure; diastolic pressure; pulse rate	
5. IEM Stabilo-Graph BP Monitor	Systolic pressure; diastolic pressure; pulse rate	
6. ForaCare D40 Blood Pressure / Glucometer	Systolic pressure; diastolic pressure; pulse rate; Blood Glucose	
7. A&D UC-321PBT	Weight	
8. A&D UC-351PBT-Ci	Weight	
9. A&D UC-352PBT-Ci	Weight	
10. A&D UC-355PBT-Ci	Weight	
11. ForaCare W320	Weight	
12. Omron HBF-510	Weight	
13. A&D UT-302PBT	Thermometer	
14. Foracare IR20b	Thermometer	
15. ChoiceMMed MD300C318T2 O2 Sensor	Oxygen saturation; pulse rate;	
16. Nonin 3230 Pulse ox	Oxygen saturation; pulse rate;	
17. Nonin 9560 Pulse ox	Oxygen saturation; pulse rate;	
18. Propeller Health Inhaler Monitor for Metered Dose Inhalers	n/a	Medication (i.e. puff) dispensed
19. Propeller Health Inhaler Monitor for Respimat	n/a	Medication (i.e. puff) dispensed
20. Propeller Health Inhaler Monitor for Discus Inhalers	n/a	Medication (i.e. puff) dispensed
21. Insung HiCare HX-461 TeleVideo Gateway with internal blood pressure monitor	Systolic pressure, diastolic pressure, pulse rate	
22. Coag-sense PT/INR Monitoring System	PT/INR	
23. Dongjin i-Scope Stethoscope	n/a	n/a
24. Medminder Maya	n/a	Medication Dispenser data
25. Medminder Jon	n/a	Medication Dispenser data
26. MXD3G Rescue Alert PERS	n/a	PERS unit activated
27. Climax	n/a	
28. H3G-700 GPRS GATEWAY	n/a	

29. H3G-650 CDMA GATEWAY	n/a	
30. H3G-800 CDMA GATEWAY	n/a	
31. Aerotel Telemodem Gateway	n/a	
32. Qualcomm 2Net Hub	n/a	
33. H3 BA-100 (J&J) Glucose Meter Adaptor	Glucose level	
34. H3 BA-110 (Nipro) Glucose Meter Adaptor	Glucose level	
35. H3 BA-110 (Bayer) Glucose Meter Adaptor	Glucose level	
36. H3 BA-110 (Abbott) Glucose Meter Adaptor	Glucose level	
37. Glooko MeterSync Blue Glucose Meter Adaptor	Glucose level	

Performance:

The Vital Caregiving System II is a software only device and the validation and verification testing were performed under the company's Design Control Process. This device meets all necessary software verification requirements in 21 CFR 820.3(z) and (aa) and 820.30(f) and (g), as described in "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." The testing has confirmed the device's conformance with specifications. The specifications do not include any significant differences from those of the predicates.

Conclusion:

The Vital Caregiving System II has the same intended use as the predicate devices. As can be seen from the comparison data and evaluations, the technology and performance characteristics for the Vital Caregiving System II are also the same as the predicate. The Vital Caregiving System II is substantially equivalent to the predicate.