September 27, 2024

AMC Health
Hernani Castro
Vice President of Quality and Process Improvement
1 World Trade Center, 85th Floor
New York, New York 10007

Re: K233446
Trade/Device Name: AMC Health CareConsole
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI, DXH
Dated: October 16, 2023
Received: October 19, 2023

Dear Hernani Castro:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233446

Device Name

CareConsole

Indications for Use *(Describe)*

CareConsole is intended to be used in conjunction with biometric health care measuring devices, mobile applications, and questionnaires to collect and store data, and for clinician-scheduled monitoring at home and/or in medical facilities. The CareConsole platform 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 healthcare professionals, authorized caregivers, and patients. Clinicians would then determine how and when to best treat their patients in response to the notifications, alerts, and biometric data. For use by individuals 12 years and older who do not have an emergency health care condition.

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

CareConsole is intended for use in capturing remote patient monitoring data from non-invasive remote monitoring devices and to provide remote hospital-at-home level of care where determined necessary by a health care professional. CareConsole is not intended for use in emergency situations or by a patient in an acute care medical facility.

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.

510(k) SUMMARY

Submitted by: Hernani Castro

Contact Person: Hernani Castro
Telephone: 914.774.5805
Email: hcastro@amchealth.com
Product Name: AMC Health CareConsole
Common Name: Patient Monitoring System
Classification: Cardiovascular, MWI, 21 CFR 870.2300; DXH, 21 CFR 870.2920

Predicate Devices:
Primary Device:
AMC Health VitalCaregiving System K151839
Additional Devices:
Vital Caregiving System K051544
AirStrip Remote Patient Monitoring K133450

Intended Use:

The AMC Health CareConsole ("CareConsole") is a software-only device used alongside vital signs monitoring devices for tracking activities and medications and for data storage, collection, and transmission.

Indications for Use:

The CareConsole is intended to be used in conjunction with biometric health care measuring devices, mobile applications, and questionnaires to collect and store data, and for clinician-scheduled monitoring at home and/or in medical facilities. The CareConsole platform 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 healthcare professionals, authorized caregivers, and patients. Clinicians would then determine how and when to best treat their patients in response to the notifications, alerts, and biometric data. For use by individuals 12 years and older who do not have an emergency health care condition.

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

CareConsole is intended for use in capturing remote patient monitoring data from non-invasive remote monitoring devices and to provide remote hospital-at-home level of care where determined necessary by a health care professional. CareConsole is not intended for use in emergency situations or by a patient in an acute care medical facility.

Device Description:

The CareConsole ("CareConsole") is a software only device. CareConsole 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 CareConsole 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.

The 3rd-party device typologies integrated into the CareConsole platform include blood pressure monitors (systolic and diastolic pressure, pulse, and, depending on the model, whether an irregular heart rhythm was detected), blood glucose meters (mg/dl blood sugar), weight scales (lbs. and kgs), thermometers (Fahrenheit and Celsius), pulse oximeters (SaO2 and pulse), prothrombin time and international normalized ratio blood testers (PT/INR), spirometers (FEV1/FEV6), and inhaler monitors (medication puff dose dispensed).

The readings from these 3rd-party devices are transmitted via one of the hub modalities described in this submission to AMC Health's servers, where they are reproduced in the CareConsole dashboard (along with both the date/time stamp on the originating 3rd-party device, and the transmission time) for review by the clinician end-user.

In addition to reproducing the raw readings from the 3rd-party devices on the CareConsole dashboard, CareConsole provides data summary tools to assist the clinician end-user in more easily visualizing data trends. These tools include summary statistics (e.g., highs, lows, averages and percentages of readings that lay outside the target parameters set by the clinician), and longitudinal graphic representations of the measurements over time periods established by the clinician end-user.

Were anything to interrupt data transfer between the 3rd-party measuring devices and CareConsole (e.g., the patient moves out of Bluetooth range to the transmission hubs before the data can be uploaded to the servers), there is no risk of data loss, due to the ability of these 3rd-party devices to store the readings locally with appropriate time/date stamps until that reconnection is made. It is for this reason that CareConsole posts both the reading date/time and the transmission date/time for each reading, so that the clinician end-user can determine if there has been a transmission lag.

Device Description:

Third Party Measurement Devices

The Subject Device has been Tested with the Following Third-Party Devices:
A&D UA-767PBT-Ci
A&D UA-767PBT-CiV
A&D UA-651BLE
A&D UA-651BLE-V
Welch Allyn RPM-BP100 1500 Series
Welch Allyn H-BP100SBP 1700 Series
A&D UC-351PBT-Ci
A&D UC-352PBT-Ci
A&D UC-355PBT-Ci
A&D UC-356BLE
ForaCare TNG-550
Omron HN-290T
Welch Allyn RPM-Scale100
Foracare IR20b
Foracare IR20b BLE
ChoiceMMed MD300C318T2 O2 Sensor
ChoiceMMed MD300C1218
Nonin 3230 Pulse ox
Nonin 9560 Pulse ox
Propeller Health Inhaler Monitor for Metered Dose Inhalers
Propeller Health Inhaler Monitor for Respimat
Propeller Health Inhaler Monitor for Discus Inhalers
Propeller Health Inhaler Monitor for Ellipta Inhalers
Propeller Health Inhaler Monitor for Symbicort Inhalers
Coag-sense PT2
Coag-Sense PT3
Mytrex MXD-LTE PERS
Mytrex MXD PERS
Securatrac MD4 mPERS
H3G-900 GATEWAY
H3G-980 GATEWAY
H3G-1000 GATEWAY
H3G-1100 Gateway
Insung HH-800a Hub
Insung HH-930 Hub
H3 BA-110 (Nipro) Glucose Meter Adaptor
H3 BA-110 (Bayer) Glucose Meter Adaptor
H3 BA-110 (Abbott) Glucose Meter Adaptor
H3 BA-110 (Roche) Glucose Meter Adaptor
H3 BA-400 Glucose Meter Adaptor
Vitalograph Lung Monitor

Device Description:

CareConsole Compatibility with Third-Party Devices

BA-110 J&J GMA
One Touch Ultra
One Touch UltraII
One Touch UltraMini
BA-110 Abbot GMA
FreeStyle Lite
FreeStyle Lite Freedom Lite
BA-110 Bayer GMA
Contour
Contour Next
A&D 767PBT-Ci Blood Pressure Device
A&D 351-PBT-ci Weight scale
Choicemed MD300C318T2 Pulse Oximeter

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	Predicate Device: AMC Health VitalCaregiving System II	Subject Device: AMC Health CareConsole
510(k) Number	**K051544**	**K133450**	**K151839**	
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)	Transmitters And Receivers, Electrocardiograph, Telephone; Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Classification Code	DXH	MWI	MWI; DXH	MWI; DXH
Regulation Number	870.2920	870.2300	870.2300; 870.2920	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 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: 1. By using a cellular	AMC Health VitalCaregiving System II is a software-only device used alongside vital signs monitoring devices for data storage, collection and transmission.	The AMC Health CareConsole is a software-only device used alongside vital signs monitoring devices for tracking activities and medications and for data storage, collection, and transmission.

		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.		
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	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	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	The CareConsole is intended to be used in conjunction with biometric health care measuring devices, mobile applications, and questionnaires to collect and store data, and for clinician-

	the physician and data can be reviewed over the Internet by physicians and patients.	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 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	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.	scheduled monitoring at home and/or in medical facilities. The CareConsole platform 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 healthcare professionals, authorized caregivers, and patients. Clinicians would then determine how and when to best treat their patients in response to the notifications, alerts, and biometric data. For use by individuals 12 years and older who do not have an emergency health care condition. • Data can be sent via intranet networks, the internet, landline telephones, cellular

		or other data.	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.	telephones, and other mobile devices. • The software supports communication between patients and clinicians, caregivers, or researchers, such as through bidirectional audio and video e-visits, telephone calls, and mobile text messages. CareConsole is intended for use in capturing remote patient monitoring data from non-invasive remote monitoring devices and to provide remote hospital-at-home level of care where determined necessary by a health care professional. CareConsole is not intended for use in emergency situations or by a patient in an acute care medical facility, and CareConsole is not for active patient monitoring.
Intended Users	Patients and physicians	Clinicians, when they	Caregivers and patients at home or in a non-acute care medical facility, and	Caregivers and patients at home or in a medical facility, and

		cannot be at the hospital	by physicians who wish to monitor and interact with patients remotely.	by physicians who wish to monitor and interact with patients remotely.
Available over the counter	No	No	No	No
Standard 60601-2-47 Medical Electrical Equipment	N/A	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 CareConsole does not continuously record and analyze ECG.
Standard EC53 ECG Trunk Cables and Patient Leadwires	N/A	N/A	N/A	The CareConsole 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	N/A	The CareConsole 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 username and strong password	Yes	Yes	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
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	Yes	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.

medical device or a partner service application.				
Data Transmission: medical device data is securely transferred via Internet between providers and the hub.	Yes	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	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, interactive voice and video response (IVVR).	Yes	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 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	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)

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-767PBT-Ci	Systolic pressure; diastolic pressure; pulse rate	
2. A&D UA-767PBT-CiV	Systolic pressure; diastolic pressure; pulse rate	
3. A&D UA-651BLE	Systolic pressure; diastolic pressure; pulse rate	
4. A&D UA-651BLE-V	Systolic pressure; diastolic pressure; pulse rate	
5. Welch Allyn RPM-BP100 1500 Series	Systolic pressure; diastolic pressure; pulse rate	
6. Welch Allyn H-BP100SBP 1700 Series	Systolic pressure; diastolic pressure; pulse rate	
7. A&D UC-351PBT-Ci	Weight	
8. A&D UC-352PBT-Ci	Weight	
9. A&D UC-355PBT-Ci	Weight	
10. A&D UC-356BLE	Weight	
11. ForaCare TNG-550	Weight	
12. Omron HN-290T	Weight	
13. Welch Allyn RPM-Scale100	Weight	
14. Foracare IR20b	Thermometer	
15. Foracare IR20b BLE	Thermometer	
16. ChoiceMMed MD300C318T2 O2 Sensor	Oxygen saturation; pulse rate;	
17. ChoiceMMed MD300C1218	Oxygen saturation; pulse rate;	
18. Nonin 3230 Pulse ox	Oxygen saturation; pulse rate;	
19. Nonin 9560 Pulse ox	Oxygen saturation; pulse rate;	
20. Propeller Health Inhaler Monitor for Metered Dose Inhalers	n/a	Medication (i.e. puff) dispensed

21. Propeller Health Inhaler Monitor for Respimat	n/a	Medication (i.e. puff) dispensed
22. Propeller Health Inhaler Monitor for Discus Inhalers	n/a	Medication (i.e. puff) dispensed
23. Propeller Health Inhaler Monitor for Ellipta Inhalers	n/a	Medication (i.e. puff) dispensed
24. Propeller Health Inhaler Monitor for Symbicort Inhalers	n/a	Medication (i.e. puff) dispensed
25. Coag-sense PT2	PT/INR	
26. Coag-Sense PT3	PT/INR	
27. Mytrex MXD-LTE PERS	n/a	PERS unit activated
28. Mytrex MXD PERS	n/a	PERS unit activated
29. Securatrac MD4 mPERS	n/a	PERS unit activated
30. H3G-900 GATEWAY	n/a	
31. H3G-980 GATEWAY	n/a	
32. H3G-1000 GATEWAY	n/a	
33. H3G-1100 Gateway	n/a	
34. Insung HH-800a Hub	n/a	
35. Insung HH-930 Hub	n/a	
36. H3 BA-110 (Nipro) Glucose Meter Adaptor	Glucose level	
37. H3 BA-110 (Bayer) Glucose Meter Adaptor	Glucose level	
38. H3 BA-110 (Abbott) Glucose Meter Adaptor	Glucose level	
39. H3 BA-110 (Roche) Glucose Meter Adaptor	Glucose level	
40. H3 BA-400 Glucose Meter Adaptor	Glucose level	
41. Vitalograph Lung Monitor	FEV1/FEV6	

CareConsole Compatibility with Third-Party Devices		
Third-Party Measuring Device	**Samsung Note 2**	**Samsung Note 3**
BA-110 J&J GMA	Third-Party Measuring Device is compatible with all uses of CareConsole run on Samsung Note 2, including biometric data collection.	Third-Party Measuring Device is not compatible with CareConsole run on Samsung Note 3 for biometric data collection. Third-Party Measuring Device is compatible with CareConsole run on Samsung Note 3 for eVisit, eMessage, and Mobile Surveys only.
One Touch Ultra		
One Touch UltraII		
One Touch UltraMini		
BA-110 Abbot GMA		
FreeStyle Lite		
FreeStyle Lite Freedom Lite		
BA-110 Bayer GMA		
Contour		
Contour Next		
A&D 767PBT-Ci Blood Pressure Device		
A&D 351-PBT-ci Weight scale		
Choicemed MD300C318T2 Pulse Oximeter		

Performance:

The CareConsole 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 conformity with specifications. The specifications do not include any significant differences from those of the predicates.

Conclusion:

The CareConsole 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 CareConsole are also the same as the predicate. The CareConsole is substantially equivalent to the predicate.