August 13, 2026

Hill-Rom, Inc.
Senthil Kumar
Sr. Manager, Regulatory Affairs
1069 State Route 46 E.
Batesville, Indiana 47006

Re: K260211
Trade/Device Name: Dashboard (P007000)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX, BZQ, FNL
Dated: August 12, 2026
Received: August 12, 2026

Dear Senthil Kumar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

JENNIFER W. SHIH -S

Jennifer 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260211 ?

Please provide the device trade name(s). ?

Dashboard (P007000)

Please provide your Indications for Use below. ?

The Dashboard is a software product indicated for use as a secondary, visual communication tool for clinical caregivers within a healthcare environment. Dashboard displays EMR data, patient location, and alarm information received from Baxter devices. The information is presented on a monitor to allow patient status and device status to be readily viewable by clinical caregivers. The Dashboard does not replace the primary monitoring, alarm, or clinical assessment functions of the connected source devices.

Please select the types of uses (select one or both, as applicable). ?

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K260211 510(k) Summary

I. SUBMITTER

Hill-Rom, Inc.
1069 State Route 46
East Batesville, Indiana 47006

Kimberly Colasanti
Assoc Dir, Regulatory Affairs
kimberly_colasanti@baxter.com

Date of Summary: 23 Jan 2026

II. SUBJECT DEVICE

Device Trade or Proprietary Name: Dashboard

Common or Usual Name: System, Network and Communication, Physiological Monitor

Regulation Number: 21CFR 870.2300

Classification Name: Cardiovascular

Primary Product Code: MSX

Associated Product code: BZQ & FNL

Class: Class II

Review Panel: Office of Cardiovascular Devices (OHT2), Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A)

III. PREDICATE DEVICE INFORMATION

Primary Predicate:

Device Trade Name: Central Station

510(k) Number: K242750

Reference Predicate:

Device Trade Name: Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense

510(k) Number: K223246

Device Trade Name: iBed Wireless with iBed Mobile

510(k) Number: K202964

IV. DEVICE DESCRIPTION

The Dashboard 2.0 is a software product indicated for use as a secondary communication measure by clinical caregivers within a healthcare environment.

(1) It is a visual communication tool to display an overview of patient data i.e., EMR data, Baxter device data and rooms/locations at nursing unit stations.

(2) This patient information is displayed on a monitor allowing patient status to be easily viewable by clinical caregivers. The Dashboard 2.0 application is not intended to prevent, diagnose, or treat illness, injury, or disease.

(3) It is used as a read-only display.

(4) The data displayed on the Dashboard 2.0 may include, but is not limited to,

- Location data (e.g. Unit, room number)
- Patient demographic, physiological, and risk data (e,g. Name, Respiratory Rate, Heart Rate, risk such as skin, pulmonary, and fall)
- Device data (e.g. rail position, brake status, bed exit, patient identification)

(5) In Dashboard 2.0 the data displayed may originate from devices and/or systems interfacing with server. The following originating source devices/systems are some examples and the information will be displays in Dashboard based on the applicability

- ADT (Admit, Discharge & Transfer of patients' data)
- EMR (Electronic Medical Record) (e.g. Epic HL7)
- Heart and Respiratory Rate monitoring System (Integrated with Centrella bed)
- Centrella bed (with or without integrated Hillrom Heart and Respiration Rate Monitoring System)
- Progressa, Progressa+ (wireless)
- Accella bed (wireless)
- Dynamo Series (Stretcher)

V. INDICATIONS FOR USE STATEMENT

The Dashboard is a software product indicated for use as a secondary, visual communication tool for clinical caregivers within a healthcare environment. Dashboard displays EMR data, patient location, and alarm information received from Baxter devices. The information is presented on a monitor to allow patient status and device status to be readily viewable by clinical caregivers. The Dashboard does not replace the primary monitoring, alarm, or clinical assessment functions of the connected source devices..

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Design verification and validation testing were performed on the Dashboard and included software verification, bench performance, and design validation. Bench performance testing was conducted to ensure the Dashboard 2.0.100 performed together according to specification. Design validation testing was conducted in a simulated-use environment by health care professionals. Users were successfully able to set and view bed status parameters from remote locations within the healthcare delivery organization as intended.

Table 1 below illustrates the comparison between the proposed device and the predicate devices.

Note: In the **Table 1**, the "Proposed Device" is defined as the Dashboard 2.0.100 device and the "Predicate Device" is defined as the Central Station (K242750) and the reference predicate devices like Hillrom Heart and Respiration Rate Monitoring System (K223246) and iBed™ Wireless with iBed™ Mobile (K202964)

Features	Proposed Device: Dashboard 2.0.100	Primary Predicate: Central Station (K242750)	Assessment of Difference
Device Trade or Proprietary Name	Dashboard	Central Station	Equivalent to primary predicate
Regulation Number	21CFR 870.2300- Cardiac monitor (including cardiotachometer and rate alarm)	21CFR 870.2300- Cardiac monitor (including cardiotachometer and rate alarm)	Equivalent to primary predicate
Product Code	**Primary Product Codes**: MSX - System, network and communication, physiological monitors **Associated Product Codes**: BZQ - Breathing Frequency Monitor FNL - AC-powered adjustable hospital bed.	**Primary Product Codes**: MSX - System, network and communication, physiological monitors **Secondary Product Codes**: MHX- Monitor, physiological, patient (with arrhythmia detection or alarms) DRQ- Amplifier and signal conditioner, transducer signal MWI Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	Equivalent to primary predicate claimed network and communication function
Class	Class II	Class II	Same
Intended Use	The Dashboard is a software product intended for use as a secondary, visual communication tool for clinical caregivers within a healthcare environment. Dashboard displays EMR data, patient location, and alarm information received from Baxter devices. The information is presented on a monitor to allow patient status and device status to be readily viewable by clinical caregivers. The	Central Station is a network device, intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters. Central Station does not perform any data processing on the data received from the Nihon Kohden compatible devices. When Central Station is connected with the Nihon Kohden bedside monitors and telemetry	Equivalent to Primary Predicate The intended use and indications for use of the proposed device and the primary predicate and reference are the same in in that they both receive patient related data from their compatible devices

Features	Proposed Device: Dashboard 2.0.100	Primary Predicate: Central Station (K242750)	Assessment of Difference
	Dashboard does not replace the primary monitoring, alarm, or clinical assessment functions of the connected source devices.	receivers/transmitters the Central Station can: • Admit and discharge patients on the Nihon Kohden network. • Display and manage compatible devices' real-time patient clinical data, vital signs, alarms and waveforms. • Review and trend data calculated by connected Nihon Kohden devices. • Store and transfer historical clinical data for the connected systems. • Print patient data. Central Station is intended for use in professional medical facilities by trained medical personnel	(beds, bedside monitors) and display that data in a consolidated screen to view each individual patient status.
Indications for Use	The Dashboard is a software product indicated for use as a secondary, visual communication tool for clinical caregivers within a healthcare environment. Dashboard displays EMR data, patient location, and alarm information received from Baxter devices. The information is presented on a monitor to allow patient status and device status to be readily viewable by clinical caregivers. The Dashboard does not replace the primary monitoring, alarm, or clinical assessment functions of the connected source devices.	Same as Intended Use	Equivalent to primary predicate The Dashboard provides secondary display of demographic, physiologic, and risk data from compatible devices and systems. Alarm generation, alarm limits, and alarm decisions remain solely on the originating devices. The Dashboard does not control therapy,

Features	Proposed Device: Dashboard 2.0.100	Primary Predicate: Central Station (K242750)	Assessment of Difference
			does not modify source data
Primary Function	One-way data communication for viewing compatible devices status parameters	One-way data communication for viewing data from the compatible devices	Equivalent to primary predicate
Intended Patient Population	Patients confirmed in the hospital and medical facility environments	Patients connected to Nihon Kohden bedside monitors, telemetry receivers, and transmitters	Equivalent to primary predicate
Intended Users	Caregivers/ Healthcare Professionals	Healthcare Professionals	Equivalent to primary predicate
Operational Environment	Intensive/Critical care Acute care Long-term care	Professional medical facilities	Equivalent to primary predicate
Primary Device Function	One-way data communication for viewing compatible devices status parameters	One -Way network device, intended to display, record and print monitored physiological data from Nihon Kohden bedside monitors, telemetry receiver and/or transmitters.	Equivalent to primary predicate But the proposed device intended to only display the patient data
Data Input	The data displayed on the dashboard originates from devices and/or systems interfacing with server. The following originating source devices/systems are some examples • EarlySense (Integrated with bed)	Configure the compatible devices with the Central Station. • NK Bedside Monitors (MHX): BSM: 1700, 3000, 6000, G9, G5, G7 • Vital Signs Monitor (MWI): SVM-7200	Equivalent to primary predicate

Features	Proposed Device: Dashboard 2.0.100	Primary Predicate: Central Station (K242750)	Assessment of Difference
	• Centrella bed (with or without integrated contact-free continuous monitoring devices) • Progressa/+ (wireless) • Accella bed (wireless)	• NK Telemetry (MHX/DRG): GZ-120/130/140 • Multiple Patient Receiver and Transmitters (DRG): ORG-9700/9100 (DRT): ZS-940, ZM-520/521/530/531 • Central Monitor (MHX): CNS6201/6801/2101	
Third -party Systems	The following originating source systems • ADT (Admit, Discharge & Transfer of patients' data) • EMR (e.g. Epic HL7)	Following functions are supported • Admit, Discharge, Pause, and Transfer functions • Patient transfer within one central station • Patient transfer between central stations • Entering patient information (Manual, Auto)	Equivalent to primary predicate.
Detailed View of Location/Status	Care Unit Details • Nursing unit name/location • Configuration name	• Hospital Name, • Bed name, • Patient name	Equivalent to primary predicate

Features	**Proposed Device: Dashboard 2.0.100**	**Primary Predicate: Central Station (K242750)**	**Assessment of Difference**
Detailed Views of patient data	Patient Status Parameters • Patient name • Patient risks • HR (Heart Rate) • RR (Respiratory rate)	Display and manage compatible devices' real-time patient clinical data, vital signs, alarms and waveforms. • Multiple Waveform, Expanded Waveform, • Trend, Tabular Trend, • Full Disclosure, • Arrhythmia Recall, • ST Recall, Event List, • Alarm Event, • ECG 12 Lead Analysis, • Hemodynamics List	Equivalent to primary predicate The patient data displayed on the subject device "Dashboard" is of less criticality compared to that displayed by the predicate device
Detailed Views of device data	Bed Parameters • Bed position status • Bed/stretcher rail status • Bed exit status • Bed low status • Bed brake status • Head of bed angle status • Therapy mode status: Type, time, reminders • Battery status: For stretchers (only) • Bed service required icon • CFCM on/off	• Trend window • Tabular Trend window • Full Disclosure window • Expanded Waveform window • Arrhythmia Recall window • ST Recall window • Event List window • Alarm Events window • ECG 12 Lead Analysis window • Hemodynamics List window • SpO2 Trend window	Equivalent to primary Predicate Data from the source devices is displayed on the Dashboard in a manner equivalent to that of the predicate device

Features	Proposed Device: Dashboard 2.0.100	Primary Predicate: Central Station (K242750)	Assessment of Difference
User Operation	• The healthcare professional initially sets bed/patient parameter settings at Dashboard setting screen. • Data is automatically received from the Server and display on the Dashboard screen.	• Central Station displays waveforms data and numerical data from a connected bedside monitor, vital sign telemeter, or multiple patient receiver unit on the screen • The parameters that display a list of measured values and a trend graph from the compatible device.	Equivalent to primary predicate

Functional Parameters comparison with Reference Predicate.

Features	Proposed Device: Dashboard 2.0.100	Reference Predicate: Hillrom Heart and Respiration Rate Monitoring System (K223246)	Reference Predicate: iBed™ Wireless with iBed™ Mobile (K202964)	Assessment of Difference
Wireless Communications – Data Transmission	Uni- Direction data transmission: From Baxter Device to server to Dashboard 2.0.000.	Uni- Direction data transmission From Device to Display in bed flip-up monitor	Bi-directional data transmission: Bed to server to iBed™ Mobile to healthcare professional and then back to iBed™ Mobile then back to server then back to bed.	Equivalent with Hillrom Heart and Respiration rate system Partially Similar to iBed Wireless with iBed Mobile

				Dashboard is not intended to change the parameters in Bed
Database	Healthcare delivery organization's central Information System Baxter Software server (Device Bridge)	There is no database involved	Healthcare delivery organization's central Information System Software server.	Equivalent to iBed Wireless with iBed Mobile
Data Input	The data displayed on the dashboard originates from devices and/or systems interfacing with Device Bridge. The following originating source devices/systems are some examples • Hillrom Heart and Respiration Rate Monitoring System (Integrated with bed) • Centrella bed (with or without integrated contact-free continuous monitoring devices) • Progressa/+ (wireless)	Analyzes and interprets information from sensor and user input and Acts as a conduit to send data (respiratory rate and heart rate) to/from bed system display	• Configure bed for wireless connection to the central healthcare Delivery Organization's Information System network server. • Install iBed™ Mobile application from relevant mobile application stores (i.e. Apple). • Configure iBed™ Mobile for use	Equivalent to Reference Predicate

	• Accella bed (wireless)			
Primary Device Function	One-way data communication for viewing compatible devices status parameters	one-way communication system intended to measure and display the patient's respiratory rate and heart rate	Bi-directional data transmission of specific bed parameters between HDO's central Information System software system	Equivalent with Hillrom Heart and Respiration rate system Partially Similar to iBed Wireless with iBed Mobile Dashboard is not intended for Bi-directional data transmission
Detailed View of information	2. Care Unit Details • Nursing unit name/location • Configuration name Patient Status Parameters • Patient name • Patient risks • HR (Heart Rate) • RR (Respiratory rate)	Patient Status Parameters • HR (Heart Rate) • RR (Respiratory rate)	Care unit viewing of: • Room location • Bed serial number Patient Status Parameters • Display Patient fall risk • Displays rounding • Displays skin Monitoring of:	Equivalent to Reference Predicate The proposed device Dashboard displays the HR and RR information from the reference Predicate" Hillrom Heart and Respiration Rate Monitoring System"

	Bed Parameters • Bed position status • Bed/stretcher rail status • Bed exit status • Bed low status • Bed brake status • Head of bed angle status • Therapy mode status: Type, time, reminders • Battery status: For stretchers (only) • Bed service required icon • CFCM on/off		• HOB angle >30 • Bed height • Nurse call connected • Brake (locked/unlocked) • Siderail position • Bed exit zone and sensitivity • Bedside and remote locking of bed motion • Bedside and remote monitoring of bed exit sensitivity • Displays assessment and score of patients fall and rotation risk	
Operational Environment	Intensive/Critical care Acute care Long-term care	Professional healthcare facilities	Healthcare delivery organization	Equivalent to Reference Predicate

Alert Indications	Visual Alert	Visible and Audible alert	Visual Alert	Equivalent to Reference Predicate Dashboard is not intended for Audible Alert.
Intended Users	Caregivers/ Healthcare Professionals	Healthcare Professionals	Healthcare Professionals	Equivalent to Reference Predicate

SUBSTANTIAL EQUIVALENCE DISCUSSION ON COMPARISON TO PREDICATE DEVICE:

Dashboard, when compared to the above predicate devices, performs similar functions with no difference in how the devices are used. The Dashboard 2.0.100 is a single medical device that performs the functions of (a) Communication and (b) displaying data from patient bed, Hillrom Heart and Respiration Rate Monitoring System (CFCM- Contact Free Continuous Monitoring), ADT & EMR.

The Dashboard 2.0.100 has the same technology characteristics in terms of transferring the data from source devices (Beds & CFCM) and the other third-party servers like ADT and EMR to Dashboard 2.0.100.

The source of energy and the features of patient and device data that is how it displayed are equivalent to predicate device.

There are minor differences in the user interface design of the proposed device, Dashboard 2.0.100, compared to the predicate devices. These modifications do not affect the device's intended use or compromise patient safety

Substantial Equivalence Discussion:

There are two differences between Predicate devices and proposed device Dashboard 2.0.100:

1. Dashboard 2.0.100 has a unique User Interface design compared to the Predicate device. That helps to show the Bed and CFCM related icons and it's easy to understand by the caregivers/Healthcare professionals.

2. Dashboard 2.0.100 is only used as a network and communication device, and it only acts as a secondary commenting (read only display) device. The information displayed in the Dashboard is from the source of patient/device data and the visual alarm is also from the source device.

These differences have no effect on substantial equivalence or the intended use of the device.

VII. NON-CLINICAL PERFORMANCE DATA

Design verification and validation testing were performed on the Dashboard device because of risk analysis and product requirements. Testing requirements included software verification, bench performance, and design validation. Software verification testing was conducted to ensure the display capability and performed according to specification. Bench performance testing was conducted to ensure the Baxter Healthcare bed software and server performed together according to specification.

Biocompatibility testing and non-clinical animal testing were not required, since Dashboard does not have direct and indirect human contact so, to demonstrate substantial equivalence to the predicate device.

The following guidance and standards were used for performance testing:

- ISO 14971Third Edition 2019-12 Medical devices - Application of risk management to medical devices (FDA consensus standard 5-125)
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION (FDA consensus standard 13-79)
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION (FDA consensus standard 5- 129)
- IEC 82304-1 Edition 1.0 2016-10 Health software – Part 1: General requirements for product safety (FDA consensus standard 13- 97)
- Content of Premarket Submissions for Device Software Functions, June 2023.
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, June 2025.
- Applying Human Factors and Usability Engineering to Medical Devices February 2016
- Postmarket Management of Cybersecurity in Medical Devices, January 2016.

VIII. CLINCAL PERFORMANCE TESTING

Clinical studies are not required because the device demonstrates substantial equivalence to a legally marketed predicate device. All differences have been addressed through risk analysis and verified via software verification, bench performance, and design validation. The intended use and fundamental technology remain unchanged. Therefore, clinical data is unnecessary to establish substantial equivalence.

IX. SUBSTANTIAL EQUIVALENCE DECISION

Based on the decision-making process outlined above and the information provided in this premarket notification, Baxter Healthcare Corporation believes the proposed Dashboard 2.0.100 is substantially equivalent, for purposes of section 510(k) of the Federal Food, Drug and Cosmetic Act only, to the predicate device(s) identified in this premarket notification.

The proposed user interface design compared to predicate devices does not have impact on the intended use or the fundamental scientific technology of the device. Per the substantial equivalence flowchart, the modified device is substantially equivalent to the currently marketed product.