November 18, 2022

Baxter Healthcare Corproration
Jigar Shah
Senior Manager, Regulatory Affairs
1069 State Route 46 East
Batesville, Indiana 47006

Re: K223246
Trade/Device Name: Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: October 20, 2022
Received: October 20, 2022

Dear Jigar Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223246

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

Indications for Use *(Describe)*
The Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense is used with compatible bed system models and is intended for continuous measurement of respiration rate (RR) and heart rate (HR) in an automatic, contact-less manner. The system is indicated for use in children, adolescents, and adults in hospitals or clinical settings. It is intended to be used for the same patient populations and the same settings, within these ranges, as the bed with which it is used. The system has been validated to withstand up to 700 lb (318 kg).

NOTE: Do not exceed the limit of the bed system for weight, population, or use setting.

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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Baxter

510(k) Summary

November 18, 2022

OWNER:

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IDENTIFICATION OF THE DEVICE:

Common Name: Heart Rate and Respiration Rate Monitoring System

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

Classification Panel: Anesthesiology

Regulation Number: (21 CFR 868.2375)

Regulation Name: Monitor, Breathing Frequency

Regulatory Class: Class II

Product Code: BZQ

PREDICATE DEVICE:

Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense

Table 1. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
Heart Rate and Respiration Rate Monitoring System	Hill-Rom, Inc.	K202018	March 4, 2021

DESCRIPTION OF THE DEVICE:

The Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense is designed for continuous and contact-free measurement of heart and respiratory rate (also referred to as Bed Sensing Unit). This device is used with a hospital bed system which is exempt from 510(k) premarket submission requirements. The Bed Sensing Unit (sensor) plugs into the bed frame to both receive power and to transmit data. Data from the System is available on the bed's graphical caregiver interface (GCI)/display unit and can be transmitted through wired and wireless communication channels to Hillrom Connectivity Solution (also known as (aka)- Hillrom Digital Health Gateway) for display, use, and storage. Additionally, the System can transmit alerts via Bloetooth to an existing hardwired Nurse Call system, speakers, and/or on/off alert lights within a bed system. The healthcare professional can adjust monitoring parameters by interacting with the bed's GCI. These parameters include hospital-defined alert thresholds, display settings, and alert configurations. The system provides alerts when patient heart rate and/or respiratory rate are recorded that are above or below the predefined thresholds.

The Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense consists of:

- The Bed Sensing Unit, placed on a bed frame under the mattress
  - This is functionally identical to the sensor cleared in K202018
- Software for data analysis, display, and input
  - The software for data analysis is identical to that cleared in K202018
  - The software for display and input is identical to the software cleared in K202018

- The device hardware, specifically the connection between the sensor and appropriate bed system
  - The hardware for the device is identical to that cleared in K202018
  - The Heart and Respiration Rate Monitoring System also uses certain hardware, such as the graphical caregiver interface and wireless communication module, of an appropriate bed system
- Hillrom Connectivity Solution (aka Hillrom Digital Health Gateway)
  - The Hillrom Digital Health Gateway consists of gateways that make information about the bed and patient available to 3rd party applications. This is functionally identical to that cleared in K202018.

INDICATIONS FOR USE:

The Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense is used with compatible bed system models and is intended for continuous measurement of respiration rate (RR) and heart rate (HR) in an automatic, contact-less manner. The system is indicated for use in children, adolescents, and adults in hospitals or clinical settings. It is intended to be used for the same patient populations and the same settings, within these ranges, as the bed with which it is used. The system has been validated to withstand up to 700 lb. (318 kg).

NOTE: Do not exceed the limit of the bed system for weight, population, or use setting.

The indications for use statement for the subject and predicate devices are identical.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense is similar to the predicate device, the Hill-Rom Vitals Monitoring System powered by EarlySense, with respect to technical characteristics, intended use, function, performance, safety and effectiveness. The differences between the predicate and subject devices do not raise new questions regarding safety or effectiveness.

Table 2. Comparison of Subject to Predicate: Technology and Specifications

Features	Heart and Respiration Rate Monitoring System *SUBJECT*	Heart and Respiration Rate Monitoring System *PREDICATE Cleared under K202018*	Assessment of Differences
FDA Product Code	BZQ	BZQ	Same
FDA Class	Class II	Class II	Same
Regulation Code	868.2375	868.2375	Same
FDA Common Names	Breathing Frequency Monitor	Breathing Frequency Monitor	Same
Measures and Displays	Respiratory Rate Heart Rate	Respiratory Rate Heart Rate	Same Same
User Interface and Display	Graphical display and interface unit integrated into a bed	Graphical display and interface unit integrated into a bed	Same
Manufacturer of Device	Hill-Rom®	Hill-Rom®	Same
Analysis Algorithms Manufacturer	EarlySense®	EarlySense®	Same
Indications for Use	The Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense is used with compatible bed system models and is intended for continuous measurement of respiration rate (RR) and heart rate (HR) in an automatic, contact-less manner. The system is indicated for use in children, adolescents, and adults in hospitals or clinical settings. It is intended to be used for the same patient populations and the same settings, within these ranges, as the bed with which it is used. The system has been validated to withstand up to 700 lb (318 kg). NOTE: Do not exceed the limit of the bed system for	The Hill-Rom Heart and Respiration Rate Monitoring System powered by EarlySense® is used with compatible bed system models and is intended for continuous measurement of respiration rate and heart rate in an automatic, contact-less manner. The system is indicated for use in children, adolescents, and adults in hospitals or clinical settings. It is intended to be used for the same patient populations and the same settings, within these ranges, as the bed with which it is used. The system has been validated to withstand up to 700 lbs (318 kg). NOTE: Do not exceed the limit of the Bed System for weight, population, or use setting.	Same

Table 2. Comparison of Subject to Predicate: Technology and Specifications

Features	Heart and Respiration Rate Monitoring System *SUBJECT*	Heart and Respiration Rate Monitoring System *PREDICATE Cleared under K202018*	Assessment of Differences
	weight, population, or use setting.		
Total System Accuracy (including undetected signals)	90% (measured as ±10% of predicate)	90% (measured as ±10% of predicate)	Same
Heart Rate	Beats per minute (BPM)	Beats per minute (BPM)	Same
Detection Range	30 – 170 BPM	30 – 170 BPM	Same
Accuracy	±4% or ±5 BPM whichever is greater	±4% or ±5 BPM whichever is greater	Same
Default Threshold Low	40 BPM	40 BPM	Same
Default Threshold High	130 BPM	130 BPM	Same
Lowest Settable Threshold	35 BPM	35 BPM	Same
Highest Settable Threshold	150 BPM	150 BPM	Same
Respiratory Rate	Breaths per minute (Br./min)	Breaths per minute (Br./min)	Same
Detection Range	6 – 45 Br./min	6 – 45 Br./min	Same
Accuracy	±4% or ±1.5 Br./min whichever is greater	±4% or ±1.5 Br./min whichever is greater	Same
Default Threshold Low	8 Br./min	8 Br./min	Same
Default Threshold High	32 Br./min	32 Br./min	Same
Lowest Settable Threshold	8 Br./min	8 Br./min	Same
Highest Settable Threshold	44 Br./min	44 Br./min	Same
Charts	Separate charts for heart rate and respiratory rate	Separate charts for heart rate and respiratory rate	Same
Time Periods	Default 8 hours Range 10 minutes to 7 days	Default 8 hours Range 10 minutes to 7 days	Same
Log	Shows a list of Log Alerts	Shows a list of Log Alerts	Same

Table 2. Comparison of Subject to Predicate: Technology and Specifications

Features	Heart and Respiration Rate Monitoring System *SUBJECT*	Heart and Respiration Rate Monitoring System *PREDICATE Cleared under K202018*	Assessment of Differences
For Use With	Hospital beds	Hospital beds	Same
Sensor	Contactless piezoelectric sensing unit	Contactless piezoelectric sensing unit	Same
Sensor Dimension (with handle)	42 x 21 x 1.4 cm	42 x 21 x 1.4 cm	Same
Weight	730 g	730 g	Same
Material	ABS & Polycarbonate	ABS & Polycarbonate	Same
Usage Life	5 years of continuous use	5 years of continuous use	Same
NOTE: Usage Life	The HR/RR Monitoring sensor must be replaced after five years of continuous use to make sure the system operates correctly. A notification will show on the GCI when it is time to replace the sensor.	The HR/RR Monitoring sensor must be replaced after five years of continuous use to make sure the system operates correctly. A notification will show on the GCI when it is time to replace the sensor.	
Water Resistance	IPX4	IPX4	Same
Manufacturer	EarlySense	EarlySense	Same
Sensor Location	Located on bed deck, under mattress – knobs to facilitate placement	Located on bed deck, under mattress – knobs to facilitate placement	Same
Hardware "Host" (Non-Sensor)	Bed System	Bed System	Same
Software for Analysis	Analyzes and interprets information from sensor and user input	Analyzes and interprets information from sensor and user input	Same
Software for Display	Acts as a conduit to send data to/from bed system display	Acts as a conduit to send data to/from bed system display	Same
Additional Capabilities	None	None	Same
Energy Source	AC power source	AC power source	Same
Backup Battery	No	No	Same
Environments	Professional healthcare facilities	Professional healthcare facilities	Same
Alert Indications	Visible and Audible	Visible and Audible	Same
Software Level of Concern	Moderate	Moderate	Same

Table 2. Comparison of Subject to Predicate: Technology and Specifications

Features	Heart and Respiration Rate Monitoring System *SUBJECT*	Heart and Respiration Rate Monitoring System *PREDICATE Cleared under K202018*	Assessment of Differences
Connectivity	Can connect to the user nurse call system though Bluetooth, and hard-wired connection. Can connect to the Hillrom Connectivity solution through both wired and wireless connection.	Can connect to the user nurse call system though hard-wired connection. Can connect to the Hillrom Connectivity solution through both wired and wireless connection.	Different; Bluetooth communication has been added for the subject device.

DISCUSSION OF NONCLINICAL TESTS:

Hill-Rom has verified and validated that the Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense meets its functional, performance, safety, and effectiveness specifications and requirements.

The following performance testing were conducted for the modification in support of the substantial equivalence determination.

- Electromagnetic compatibility (EMC) - EMC testing were conducted on the Hillrom™ Heart and Respiration Rate Monitoring System powered by EarlySense and was tested as an accessory to the bed with which it is currently used. The System is intended for intensive/critical care, acute care, long term care, and outpatient (ambulatory) care environments. The System is not intended for domestic / home care environments. The subject device incorporates wireless functionality. Testing was conducted using standard US power input of 120 volts and 60 hertz frequency, where applicable. The system complies with IEC 60601-1-2 standard for EMC.

- Software Verification and Validation Testing - Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern since a failure or latent flaw in the software could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

- Cybersecurity Testing - Cybersecurity concerns for monitoring system were addressed in accordance with FDA's "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff" document issued October 2, 2014.

- Coexistence Testing - Wireless coexistence testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Radio Frequency Wireless Technology in Medical Devices" and the IEEE/ANSI C63.27 American National Standard for Evaluation of Wireless Coexistence. The wireless coexistence testing was performed to verify that the subject device meets the acceptance criteria for wireless coexistence.

CONCLUSION:

The HR/RR Monitoring System is similar to the predicate device with respect to features, technical characteristics, intended use, and indications for use. The differences do not raise additional or different questions of safety or effectiveness. Extensive testing has been conducted on the finished Hillrom Heart and Respiration Rate Monitoring System powered by EarlySense and demonstrates that the System is as safe and as effective as the predicate device.