March 4, 2021

Hill-Rom, Inc.
Jigar Shah
Regulatory Affairs Manager
1069 State Route 46 East
Batesville, Indiana 47006

Re: K202018
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: February 3, 2021
Received: February 5, 2021

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, Ph.D.
Assistant Director
DHT1C: Division of ENT, 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)*
K202018

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.**

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.***

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*"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

Section 5

## I. SUBMITTER

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

Phone: 919-743-1170
Fax: 812-934-1675

Contact Person: Jigar Shah
Date Prepared: February 1, 2021

## II. DEVICE

Name of Device: Hillrom™ Heart and Respiration Rate Monitoring System powered by EarlySense
Common or Usual Name: Heart Rate and Respiration Rate Monitoring System
Classification Name: Breathing Frequency Monitor (21 CFR 868.2375)
Regulatory Class: II
Product Code: BZQ

## III. PREDICATE DEVICE

Hill-Rom® Vitals Monitoring System powered by EarlySense® (K180079)

## IV. DEVICE DESCRIPTION

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 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 K180079
- Software for data analysis, display, and input
  - The software for data analysis is identical to that cleared in K180079
  - The software for display and input is identical to the software cleared in K180079
- The device hardware, specifically the connection between the sensor and appropriate bed system
  - The hardware for the device is identical to that cleared in K180079
  - 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

The data provided by this system is intended to aid a clinician in the evaluation process of a patient's clinical status and should be interpreted by a healthcare professional only. The Hillrom™ Heart and Respiration Rate Monitoring System powered by EarlySense has not been studied on any specific patient group, nor has it been studied as a diagnostic tool for any specific disease or medical condition. It is meant as an adjunctive tool only for contact-free measurement of respiration rate and heart rate.

## V. INTENDED USE/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.

## VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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 1: Comparison of Subject to Predicate: Technology and Specifications**

| Element | Heart and Respiration Rate Monitoring System (Subject) | Vitals Monitoring System (Predicate K180079) | Comparison |
|---|---|---|---|
| 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 | Respiratory Rate | Same |

| Element | Heart and Respiration Rate Monitoring System (Subject) | Vitals Monitoring System (Predicate K180079) | Comparison |
|---|---|---|---|
| | Heart Rate | Heart Rate | 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).<br><br>NOTE: Do not exceed the limit of the bed system for weight, population, or use setting. | 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).<br><br>NOTE: Do not exceed the limit of the Bed System for weight, population, or use setting. | Same |
| Total System Accuracy (including undetected signals) | 90% | 90% | 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 |

| Element | Heart and Respiration Rate Monitoring System (Subject) | Vitals Monitoring System (Predicate K180079) | Comparison |
|---|---|---|---|
| Charts | Separate charts for heart rate and respiratory rate | Separate charts for heart rate and respiratory rate | Same |
| Time Periods | Default 8 hours<br>Range 10 minutes to 7 days | Default 8 hours<br>Range 10 minutes to 7 days | Same |
| Log | Shows a list of Log Alerts | Shows a list of Log Alerts | Same |
| 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 year of continuous use | 1 year of continuous use | Different |
| 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 EarlySense sensor must be replaced after one year 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 |
| Connectivity | 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. | Can connect to customer nurse call system through a hard-wired connection. | Different |

## VII. PERFORMANCE DATA

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 data were provided 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.

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.

Usage Life Testing
Usage Life testing was conducted to demonstrate extended usage life of the bed sensor from 1 year to 5 years.

## VIII. CONCLUSIONS

Extensive testing has been conducted on the finished Hillrom™ Heart and Respiration Rate Monitoring System powered by EarlySense and demonstrate that the System is as safe, as effective, and performs as well as the predicate device. 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.
Clinical testing was not required to demonstrate substantial equivalence.