May 7, 2018

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

Re: K180079
Trade/Device Name: Hill-Rom® 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: April 4, 2018
Received: April 5, 2018

Dear Sarah Fitzgerald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180079

Device Name
Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense®

Indications for Use *(Describe)*
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.

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.

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510(k) Summary: Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense®

Date Prepared:	May 7, 2018
Company	Hill-Rom, Inc. 1069 State Route 46 East Batesville, IN 47006
Contact	Sarah Marie Fitzgerald Regulatory Affairs Manager 812-931-2924 (telephone)
Device Trade Name	Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense®
Device Common Names	Breathing Frequency Monitor
Device Regulation	21 CFR 868.2375
Classification	Product Code: BZQ; Panel Code 73; Regulatory Class II
Predicate Device	EarlySense Ltd. EarlySense® Insight System; Product Code BZQ; K152911

Purpose:
The purpose of this submission is to request clearance for the Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense®.

Device Description:
The Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® is designed for continuous and contact-free measurement of heart and respiratory rate. This device is used with a hospital bed system which is exempt from premarket submission requirements. The Bed Sensing Unit (sensor) attaches to the bed frame and plugs into the bed to both receive power and to transmit data to the bed's graphical user interface/display unit. Additionally, the System can send alarms to an existing hardwired Nurse Call system, speakers, and/or on/off alarm lights within a bed system. The healthcare professional is able to adjust monitoring parameters by interacting with the bed's graphical user interface/display. These parameters include alarm thresholds, display settings, and alarm configurations. The system provides alarm when patient heart rate and/or respiratory rate excurse above or below the predefined thresholds.

The Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® consists of:

- The Bed Sensing Unit, placed on the bed frame under the mattress
    - This is functionally identical to the sensor cleared in K152911
- Software for data analysis, display, and input
    - The software for data analysis is identical to that cleared in K152911
- The device hardware, specifically the connection between the sensor and appropriate bed system
    - The System also uses the graphical user interface of an appropriate bed system.

The data provided by this system is intended to provide trending information on monitored parameters which should be interpreted by a healthcare professional only. The Hill-Rom® 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 measuring respiration rate and heart rate. The system helps healthcare

professionals detect unanticipated patient deterioration quickly by providing heart and respiratory rate continuously rather than through standard periodic caregiver rounding.

Indications for Use:
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.

Performance Data:
Hill-Rom has verified and validated that the Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® meets its functional, and performance specifications and requirements. Software and hardware testing of components as well as the final device have been conducted. The device has been tested for compliance to International Standards including the following:

- IEC/AAMI/ANSI/ES 60601-1 : Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance : Edition 3.1
- IEC 60601-1-2 : Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests : Edition 4.0
- IEC 60601-1-6 : Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability : Edition 3.1
- IEC 60601-2-49 : Particular Requirements for the Basic Safety and Essential Performance of Multifunction Patient Monitoring Equipment : Edition 2.0
- ISO 14971 : Medical Devices – Application of Risk Management to Medical Devices : 2012 (covers ANSI/AAMI/ISO 14971:2007/(R)2010)
- AAMI/ANSI HE75 : Human Factors Engineering – Design of Medical Devices : 2009
- AAMI/ANSI/IEC 62366-1 : Medical Devices – Part 1: Application of Usability Engineering to Medical Devices : 2015
- AAMI/ANSI/IEC 62304 : Medical Device Software – Software Life Cycle Processes : 2006
- Human Factors evaluation was conducted per FDA guidance document “Applying Human Factors and Usability Engineering to Medical Devices”

Durability testing was conducted to demonstrate the sensor can withstand weight up to 700 lbs. Additionally, heart rate and respiration rate verification was conducted to determine the accuracy of the system compared to the predicate.

The extensive performance testing that has been conducted demonstrate that the System is equivalent to the predicate device. No clinical testing was performed.

Technological Characteristics:
The Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® has the substantially equivalent technological characteristics as the predicate device, as summarized on the table below.

Technological Characteristic	Subject Device	Predicate / Reference Device (K152911 unless noted)	Comparison
Indications for Use	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 EarlySense® 2.0 System is intended for continuous measurement of respiration rate, heart rate and movement in an automatic, contact-less manner at a home, hospital or clinical setting. The system is indicated for use in children, adolescents, and adults. The operation of the EarlySense® 2.0 System has been studied in children (weight ≥ 22 lbs [10 kg]) and adults (weight < 245 lbs [111 kg]) during sleep and resting conditions.	Equivalent: Additional wording relevant to use with a bed system.
	The system has been validated to withstand up to 700 lbs (318 kg).	[Elsewhere in Manual: Do not use the EarlySense® 2.0 System for patients who weigh more than 200 kg (440 lbs)]	Different: Testing provided
	NOTE: Do not exceed the limit of the Bed System for weight, population, or use setting.	In addition, the EarlySense® 2.0 System can continuously monitor oxygen saturation of Arterial Hemoglobin (SpO2) using Pulse Oximetry in pediatric (ages 2 years and older), adolescents and adults at a home, hospital, or clinical setting.	Different: Within the scope of the predicate capabilities.
For Use With	Hospital Beds	Hospital Beds and Chairs	Similar
Sensing Unit	Contactless, piezoelectric sensing unit	Contactless, piezoelectric sensing unit	Same
Bedside Display	Utilizes bed system display	K152911: No bedside display K131379: Stand-alone bedside display	Equivalent
Sensing and Analysis Algorithms	Proprietary, developed by EarlySense®	Proprietary, developed by EarlySense®	Same
Respiratory Rate Range	6 – 45 Breaths/minute	6 – 45 Breaths/minute	Same
Heart Rate Range	30 – 170 beats per minute	30 – 170 beats per minute	Same
Performance Testing	IEC/AAMI/ANSI/ES 60601-1 IEC 60601-1-2 IEC 60601-1-6	IEC/AAMI/ANSI/ES 60601-1 IEC 60601-1-2 IEC 60601-1-6	Same

Technological Characteristic	Subject Device	Predicate / Reference Device (K152911 unless noted)	Comparison
	IEC 60601-2-49 ISO 14971 AAMI/ANSI HE75 AAMI/ANSI/IEC 62366-1 AAMI/ANSI/IEC 62304 Durability Testing (Sensor) Accuracy Testing	IEC 60601-2-49 ISO 14971 AAMI/ANSI HE75 AAMI/ANSI/IEC 62366-1 AAMI/ANSI/IEC 62304 Durability Testing (Sensor) Accuracy Testing	

Basis of Substantial Equivalence / Conclusion:
The Hill-Rom® Heart and Respiration Rate Monitoring System powered by EarlySense® is similar and substantially equivalent to the predicate device with respect to technological characteristics, intended use, function, and performance. The information provided within this premarket notification supports substantial equivalence to the predicate device.