May 1, 2018

PeraHealth, Inc.
% Donna-Bea Tillman
Senior Consultant
Biologics Consulting
1555 Kingh Street, Suite 300
Alexandria, Virginia 22314

Re: K172959
Trade/Device Name: PeraServer™ and PeraTrend™ System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: March 29, 2018
Received: March 29, 2018

Dear Donna-Bea Tillman:

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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K172959

Device Name
PeraServer and PeraTrend System

Indications for Use *(Describe)*
The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to compute a patient status index. The Rothman Index is a single measure of a patient's physiologic condition based on the aggregate statistical mortality risk associated with the values of the patient's vital signs, nursing assessments, and selected lab values.

PeraServer is indicated for use wherever there is interest in generating Rothman Index (RI) scores and/or associated configurable warnings.

PeraTrend is indicated for use by healthcare providers whenever there is need for displaying and/or trending RI scores and displaying associated configurable warning states as an adjunct to clinical decision support.

PeraServer/PeraTrend is intended for the care of patients throughout the hospital setting (e.g., in the emergency department, on the wards, in intensive care units).

The Rothman Index score is validated for use with neonatal, pediatric, and adult patients. It is an adjunct-to and is not intended to replace vital signs monitoring and is not intended for use in the Neonatal Intensive Care Unit.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the PeraServer and PeraTrend System is provided below:

Device Common Name:	Adjunct to Multiparameter Patient Monitor
Device Trade Name:	PeraServer™ and PeraTrend™ System
Applicant:	PeraHealth, Inc. 6302 Fairview Road, Suite 310 Charlotte, NC 28210
Contact:	Joseph Beals, Ph.D. Vice President, Informatics jbeals@perahealth.com
Prepared by:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting Group, Inc. dtillman@biologicsconsulting.com
Date Prepared:	April 26, 2018
Classification Regulation:	21 CFR 870.2300 (Class II)
Regulation Description:	Cardiac Monitor (including Cardiotachometer and Rate Alarm)
Panel:	Cardiovascular
Product Code:	MWI
Product Code Description:	Physiological Patient Monitor (without arrhythmia detection or alarms)
Predicate Device:	BedsidePEWS (K124038)

1. INDICATIONS FOR USE:

The indications for use for the PeraServer and PeraTrend System are the following:

> "The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to compute a patient status index. The Rothman Index is a single measure of a patient's physiologic condition based on the aggregate statistical mortality risk associated with the values of the patient's vital signs, nursing assessments, and selected lab values.

PeraServer is indicated for use wherever there is interest in generating Rothman Index (RI) scores and/or associated configurable warnings.

PeraTrend is indicated for use by healthcare providers whenever there is need for displaying and/or trending RI scores and displaying associated configurable warning states as an adjunct to clinical decision support.

PeraServer/PeraTrend is intended for the care of patients throughout the hospital setting (e.g. in the emergency department, on the wards, in intensive care units).

The Rothman Index score is validated for use with neonatal, pediatric, and adult patients. It is an adjunct-to and is not intended to replace vital signs monitoring and is not intended for use in the Neonatal Intensive Care Unit."

2. DEVICE DESCRIPTION:

The subject of this submission is the **PeraServer and PeraTrend System**, consisting of:

- **PeraServer** – a backend hardware/software platform that imports electronic health record (EHR) data, which are used to compute and store **Rothman Index** (RI) scores and related measures
- **PeraTrend** – the frontend web-based user interfaces for displaying RI scores and related measures, as well as simple manipulations of the display (i.e., graphical representations over time, comparison of Rothman Index scores and input measures)

PeraServer and PeraTrend are software-only devices that are installed on user-provided hardware.

3. SOFTWARE:

Documentation has been provided in the submission commensurate with a **Moderate** Level of Concern.

4. SUBSTANTIAL EQUIVALENCE:

4.1. Cited Predicate Device:

The cited predicate device is the Bedside Clinical Systems Bedside Paediatric Early Warning System (BedsidePEWS), cleared under K124038.

4.2. Comparison of Intended Use:

The PeraServer and PeraTrend System and the predicate BedsidePEWS have the same intended use, namely to provide healthcare providers with a patient status index that reflects the underlying patient condition. Both devices acquire their inputs from the hospital Electronic Medical Record System and are intended to be an adjunct to vital signs monitoring. Both devices are intended to be used by healthcare professionals in the clinical care environment. The intended patient population of BedsidePEWS is the pediatric population, while the PeraServer

and PeraTrend System is intended for both pediatric and adult populations. This difference in indications does not raise different questions of safety and effectiveness.

4.3. Comparison of Technological Characteristics:

	Subject Device	**Predicate Device**
Manufacturer	PeraHealth, Inc.	Bedside Clinical Systems, Inc.
Device Name	PeraServer™ and PeraTrend™ System	Bedside Paediatric Early Warning System (BedsidePEWS™)
Classification Regulation	21 CFR 870.2300, Class II	21 CFR 870.2300, Class II
Product Code	MWI: Physiological Patient Monitor (without arrhythmia detection or alarms)	MWI: Physiological Patient Monitor (without arrhythmia detection or alarms)
Device Description	PeraServer collects specified demographic and clinical data from the EHR and ancillary systems. PeraServer computes an Early Warning Score called the Rothman Index (RI), determines if RI scores and/or clinical criteria meet configurable EWS criteria; specified input data, and RI score and warning states are stored for analysis, remote viewing, and interfacing. PeraTrend provides a web-based user-interface for trending and review of RI scores and underlying data and warning status. PeraServer/PeraTrend also interface to other medical automation systems such as the Hospital Electronic Health Record (EHR).	BedsidePEWS is a web-based clinical decision-support tool that can also be run as a standalone application for use on computers running Microsoft Software Operating features with a local network connection, which access medical data. It is also interfaces to other medical automation systems such as Hospital Information System (HIS), Electronic Medical Record (EMR), and Practice Management Software.

	Subject Device	Predicate Device
Indications for Use	The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to compute a patient status index. The Rothman Index is a single measure of a patient's physiologic condition based on the aggregate statistical mortality risk associated with the values of the patient's vital signs, nursing assessments, and selected lab values. PeraServer is indicated for use wherever there is interest in generating Rothman Index (RI) scores and/or associated configurable warnings. PeraTrend is indicated for use by healthcare providers whenever there is need for displaying and/or trending RI scores and displaying associated configurable warning states as an adjunct to clinical decision support. PeraServer/PeraTrend is intended for the care of patients throughout the hospital setting (e.g. in the emergency department, on the wards, in intensive care units). The Rothman Index score is validated for use with neonatal, pediatric, and adult patients. It is an adjunct-to and is not intended to replace vital signs monitoring and is not intended for use in the Neonatal Intensive Care Unit.	The Bedside Paediatric Early Warning System (BedsidePEWS) is an electronic documentation tool that is designed to be used in conjunction with multi-parameter patient monitoring. It is indicated for use by healthcare professionals with paediatric patients between the ages of term newborn (>37 weeks gestational age) and 18 years, who are hospitalized with any medical or surgical condition. BedsidePEWS allows input by the healthcare professional of commonly recorded vital sign data and provides clinician with a patient status index (the "BedsidePEWS score") based on a weighted average of seven vital signs when entered by the clinician, namely Heart Rate, Respiratory Rate, Blood Pressure, Oxygen Saturation, Oxygen Therapy, Respiratory Effort, and Capillary Refill. The "BedsidePEWS score" is a single measure of a patient's condition and indicates the variation in the patient's vital signs with respect to normality. BedsidePEWS is an adjunct-to and is not intended to replace vital signs monitoring. BedsidePEWS is intended for use in wards and emergency rooms in hospitals that provide care for children between the ages of term newborn (>37 weeks gestational age) and 18 years. It is not intended for use in the Neonatal Intensive Care Unit.
Intended users	Healthcare Professionals	Healthcare Professionals
Patient Population	Adult and pediatric patients	Pediatric patients between the ages of term newborn (>37 weeks gestational age) and 18 years
Use environment	Hospital	Hospital
Parameters	Vital signs (Temp, Sys. BP, Dias. BP, HR, RR) Pulse-ox, heart rhythm*, nursing assessments, Braden score, selected labs (potassium, sodium, creatinine, chloride, WBC, BUN, HGB)	Vital signs (Heart Rate, Respiratory Rate, Blood Pressure, Oxygen Saturation, Oxygen Therapy, Respiratory Effort, and Capillary Refill)

	Subject Device	Predicate Device
Score	Rothman Index (RI) and Pediatric RI (pRI)	BedsidePEWS score
Material	Software only	Software only
Hardware Platform	PeraServer/PeraTrend require dedicated application and database servers.	Windows PC or Tablet
Data Source	Hospital EHR systems	Hospital EHR systems or manually input
Data Display	PeraTrend Web – a browser based display PeraTrend Kiosk – a browser based display configured for dedicated monitors providing an always-up, auto-refreshed display PeraTrend EHR – a browser based display accessed and viewed from within the EHR	Browser based display
Ability to trend	Yes	Yes
Real-time display	Yes	Yes
Privacy	HIPPA compliant	HIPPA compliant

**Note: Although the PeraServer and PeraTrend System uses heart rhythm as one of its inputs, this information is obtained from the EHR and therefore the PeraServer and PeraTrend System is not performing arrhythmia detection.*

5. PERFORMANCE TESTING:

To demonstrate the validity of the RI score, three retrospective studies are described in the submission:

- Rothman et. al (2013), to describe the mechanics and validation of the adult RI score
- Finlay et. al (2014), to provide a comparison between RI scores and MEWS
- Rothman et. al (2017), to describe the mechanics and validation of the pediatric RI score

These studies demonstrate that the performance of the PeraServer and PeraTrend System is equivalent to that of the predicate device for both pediatric and adult populations.

6. CONCLUSION:

The subject PeraServer and PeraTrend System and the predicate BedsidePEWS have the same intended use, which is to provide healthcare providers with a patient status index that reflects the

underlying patient condition. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the results of performance testing demonstrate that the PeraServer and PeraTrend System performs in accordance with specifications and meets user needs and intended uses. The software testing provided in the submission verifies the functionality of the software, and the studies provided in the submission validate the Rothman Index score. Therefore, the PeraServer and PeraTrend System has been demonstrated to be substantially equivalent to the predicate BedsidePEWS.