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

Re: K183370
Trade/Device Name: PeraMobile and PeraWatch System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: July 25, 2019
Received: July 26, 2019

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. 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,

for Stephen Browning
Acting 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

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)*
K183370

Device Name
PeraMobile and PeraWatch System

Indications for Use *(Describe)*

PeraMobile Indications for Use:

The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to provide 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.

PeraMobile is indicated for use by healthcare providers within the hospital for displaying and/or trending Rothman Index (RI) scores and displaying associated configurable warning states as an adjunct to clinical decision support.

PeraMobile is intended for use in the hospital to support Rapid Response Team clinicians or other dedicated clinical response staff responsible for pro-actively rounding on patients of concern and/or providing supplemental support to bed-side clinicians.

PeraWatch Indications for Use:

The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to provide 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.

PeraWatch is indicated for use by healthcare providers whenever there is need within the hospital for displaying and/or trending Rothman Index (RI) scores and displaying associated configurable warning states as an adjunct to clinical decision support.

PeraWatch is intended to support clinicians in surveilling patients throughout the hospital setting (e.g. in the emergency department, on the wards, in intensive care units) and across multiple hospitals in a centralized and/or remote professional clinical surveillance 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.

510(K) SUMMARY

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

Device Common Name:	Adjunct to Multiparameter Patient Monitor
Device Trade Name:	PeraMobile and PeraWatch System
Applicant:	PeraHealth, Inc. 6302 Fairview Road, Suite 310 Charlotte, NC 28210
Contact:	Brad Coleman Chief Information Officer bcoleman@perahealth.com
Prepared by:	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting Group, Inc. dtillman@biologicsconsulting.com
Date Prepared:	December 4, 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:	PeraTrend (K172959)
Reference Device:	AlertWatch:OB (K173715)

1. INDICATIONS FOR USE:

The indications for use for PeraMobile are the following:

The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to provide 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.

PeraMobile is indicated for use by healthcare providers within the hospital for displaying and/or trending Rothman Index (RI) scores and displaying associated configurable warning states as an adjunct to clinical decision support.

PeraMobile is intended for use in the hospital to support Rapid Response Team clinicians or other dedicated clinical response staff responsible for pro-actively rounding on patients of concern and/or providing supplemental support to bed-side clinicians.

The indications for use for PeraWatch are the following:

The Rothman Index uses commonly recorded vital sign, nursing assessment, and lab data to provide 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.

PeraWatch is indicated for use by healthcare providers within the hospital for displaying and/or trending Rothman Index (RI) scores and displaying associated configurable warning states as an adjunct to clinical decision support.

PeraWatch is intended to support clinicians in surveilling patients throughout the hospital setting (e.g. in the emergency department, on the wards, in intensive care units) and across multiple hospitals in a centralized and/or remote professional clinical surveillance setting.

2. DEVICE DESCRIPTION:

PeraMobile is an interactive mobile application that provides an interface to display RI scores, trends, and configurable warnings for selected groups of patients within the hospital. PeraMobile reads and writes data directly to and from the PeraServer database. Designed for mobile clinicians, PeraMobile functionality also allows end-users to document both pre-defined interventions and free text notes that are stored in PeraServer and accessible through the user interface within PeraMobile. PeraServer was previously cleared in K172969.

PeraWatch is a read-only, web-based graphical user interface for displaying Rothman Index scores, trends and configurable warnings. PeraWatch reads data directly from the PeraServer database.

PeraMobile and PeraWatch are software-only devices that are installed on user-provided hardware that supports IEEE 802.11b or higher (802.11ac is recommended). PeraHealth has conducted load tests to determine expected payload sizes and acceptable response times. Throughput is calculated based on the default 5 second refresh rate, which is configurable by hospital IT administration. Based on the 1.33 Gbit/s specification of 802.11ac, PeraMobile will support 346MM simultaneous patient updates. In other words, a typical 500 bed hospital will only use .0014% of available bandwidth. 802.11ac will support distances of up to 400 feet with minimal data degradation. Most hospitals strive for 100 feet between access points.

3. SOFTWARE:

Software verification and validation testing was 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."

4. SUBSTANTIAL EQUIVALENCE:

4.1. Cited Predicate Device:

The cited predicate device is PeraTrend, cleared under K172959.

4.2. Comparison of Intended Use:

Both the subject PeraWatch and PeraMobile devices and the predicate PeraTrend device rely on PeraServer to calculate an RI score. The subject and predicate devices are both secondary patient monitoring devices intended for displaying and trending the RI score and associated warnings as an adjunct to clinical decision support for healthcare professionals throughout the hospital setting.

PeraWatch and PeraMobile are also indicated for use for use by healthcare professionals working in a professional care setting to augment and support bedside clinicians by providing a second pair of eyes on the evolving patient condition. PeraWatch and PeraMobile are not intended to replace or substitute for any of the usual care measures provided by primary or direct care givers working in the facility and at the bedside. The functionality provided by PeraWatch and PeraMobile can only augment, but not detract from, existing care standards, and the use of these products does not introduce new risks. Therefore, the differences in indications for use do not constitute a new intended use, and PeraTrend can be used as a primary predicate device for PeraWatch and PeraMobile.

4.3. Comparison of Technological Characteristics:

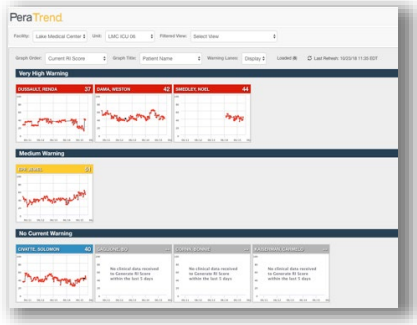
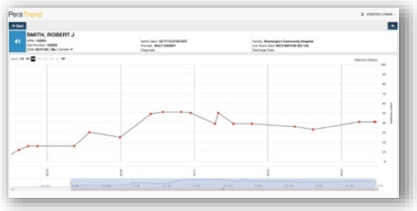
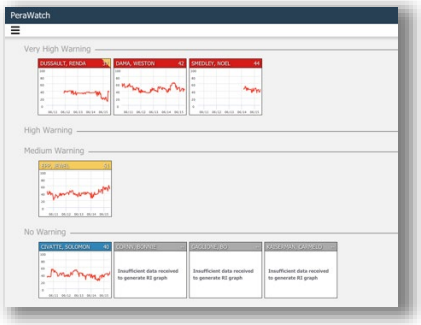
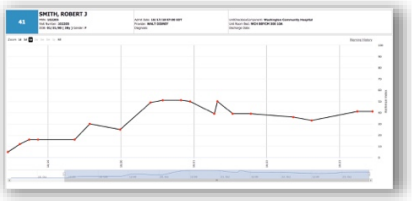
	Primary Predicate	Subject Device	Discussion of Differences
510(k) Number	K172959	K183370	N/A
Manufacturer	PeraHealth, Inc.	PeraHealth, Inc.	Same
Device Name	PeraServer and PeraTrend System	PeraWatch and PeraMobile Systems	N/A
Classification Regulation	21 CFR 870.2300, Class II	21 CFR 870.2300, Class II	Same
Product Code	MWI (Physiological Patient Monitor (without arrhythmia detection or alarms)	MWI (Physiological Patient Monitor (without arrhythmia detection or alarms)	Same
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).	**PeraWatch** is a read-only web-based graphical user interface for displaying Rothman Index (RI) scores, trends and configurable warnings. PeraWatch reads data directly from the PeraServer database. **PeraMobile** is an interactive mobile application that displays RI scores, trends and configurable warnings for selected groups of patients within the hospital. PeraMobile reads and writes data directly to and from the PeraServer database.	PeraTrend, PeraWatch, PeraMobile all run from data supplied by PeraServer. Functional differences: Differences are primarily in the pushed warning notifications to the PeraWatch and PeraMobile. PeraWatch array view provides a graph header indicator to show patients with recently changed warning states. PeraMobile runs on a mobile device app, supports out-of-app notifications of patients changing warnings state, and the display of data is modified for ease-of-use on smaller screens.
Intended users	Healthcare Professionals	Healthcare Professionals	Same

	Primary Predicate	Subject Device	Discussion of Differences
Patient Population	Adult and pediatric patients	Adult and pediatric patients	Same
Use environment	Hospital	Throughout Hospital and centralized and/or remote professional clinical surveillance setting.	PeraTrend and PeraWatch are for use in the hospital. PeraMobile could be used in hospital or remotely (e.g. in a centralized setting) for surveilling patients who are in multiple different facilities. It cannot be used in a home use setting because it requires connection to a hospital WiFi to operate.
Primary or Secondary Monitoring	Only intended for secondary monitoring.	Only intended for secondary monitoring.	Same
RI score calculation	RI score is calculated by PeraServer	RI score is calculated by PeraServer	Same
Notes/Interventions	PeraTrend does not allow user to enter notes or interventions.	PeraWatch does not allow user to enter notes or interventions. PeraMobile allows user to enter notes and select intervention actions from a dropdown menu.	Ability to enter notes and select interventions in PeraMobile does not impact the RI or RI-warnings or how they are acted upon. The notes and intervention entry permit activity tracking and reporting to be provided to managers for quality and process improvement purposes.
Warning States	Warnings states for patients are calculated by PeraServer for use by PeraTrend.	Warning states for patients are calculated by PeraServer for use by PeraWatch and PeraMobile	Same
Patient List View	No list view; does support multiple patient graph view.	PeraWatch has no list view; does support multiple patients graph view. PeraMobile does have a text-based patient list view.	Difference is in PeraMobile – screen real-estate does not support a graph array view and hence a text-based patient list view is provided instead.

	Primary Predicate	Subject Device	Discussion of Differences
Watchlist View	No watchlist view available.	PeraWatch does not have a watchlist view available. PeraMobile allows user to select patients to go onto a custom "watchlist".	The PeraMobile "watchlist" is to support mobile clinicians who have more limited access to a computer and need a convenient way to track patients of interest for follow-up purposes.
Single Patient View	PeraTrend provides a patient specific single-graph view of RI-scores trended over time.	PeraWatch and PeraMobile provide a patient specific single-graph view of RI-scores trended over time. PeraWatch graph header uses color to indicate both patient's current warning status and prior warning status if changed in the last four hours.	Graph appearance and functionality is *nearly* identical between PeraTrend and PeraWatch.
Array view	PeraTrend provides an array view of multiple patients using small graph icons.	PeraWatch array view is the same as PeraTrend array view *with the addition* of header color to indicate prior warning status if changed in the last four hours. PeraWatch also allows a "tile view" in which graph thumbnails are replaced by squares showing current RI score value and color coded according to patient's current warning state, if any. PeraMobile includes a patient list view.	PeraWatch use of color to show prior warning state if changed in last four hours is an aid to PeraWatch users for identifying patients getting better or worse (based on warning state) given the very large number of patients they are viewing. The PeraWatch "tile" view is to facilitate ease of viewing for large volume surveillance (i.e. hundreds of patients) across facilities. PeraMobile difference is to make the multi-patient viewing options more user-friendly on a smaller device window (i.e. mobile device).
Provides Clinical Advisories	Clinical Advisories (warning states) are generated by PeraServer which computes RI scores and assigns warning states based on configured settings.	Clinical Advisories (warning states) are generated by PeraServer which computes RI scores and assigns warning states based on configured settings.	No difference in how clinical advisories are generated

	Primary Predicate	Subject Device	Discussion of Differences
Graph-based indicator of Patient Warning Status	PeraTrend graphs have a colored header and text indicating patient warning state.	PeraWatch and PeraMobile graphs have a colored header and text indicating patient warning state.	Same
In App Warning Notifications	Users can see patient warning state by viewing graphs within the PeraTrend application.	Users can see patient warning state by viewing graphs within the PeraWatch or PeraMobile application. PeraWatch and PeraMobile include a notification list of patients with new warnings. PeraMobile can also display pop-up notifications.	PeraTrend is intended for users to look at small numbers of graphs, e.g. corresponding to nurse or physician assignments, or a nursing unit, where there is direct familiarity with patients and it is easy to see patient warning states. PeraWatch is for oversight of large volumes of patients, and it can be difficult to keep track of who has recently escalated in warning level – the notifications list provides that information directly to the user. PeraMobile is for mobile clinicians viewing patients throughout the facility, and they may not be accessing the EHR or otherwise looking at patient RI graphs. The in-app notification tracking allows them to easily keep track of a patient on their list that has escalated in warning level. The use of In App Notifications is similar to the reference device, AlertWatch:OB (K173715), which also provides warning alerts to mobile devices.
Out of App "pushed" Warning Notifications	None	PeraMobile has an Out-of-App notification that identifies when a patient has a change to a higher warning state.	PeraMobile is for mobile clinicians viewing patients throughout the facility, and they may not be accessing the EHR or otherwise looking at patient RI graphs. The out-of-app notifications allows them to easily know when a patient on their list has escalated in warning level.

	Primary Predicate	Subject Device	Discussion of Differences
Timeliness of Warning (Alert) Calculation	Calculated when data is available to PeraServer from source system; warning generation subject to data entry delays.	Calculated when data is available to PeraServer from source system; warning generation subject to data entry delays.	Same
Timeliness of Warning (Alert) Availability	Once a warning is generated in PeraServer, it is immediately available via PeraTrend.	Once a warning is generated in PeraServer, it is immediately available via PeraWatch and PeraMobile. The user will receive an out-of-app notification in the case of PeraMobile.	Same
Material	Software only	Software only	Same
Hardware Platform	PC	PC, iPhone	PeraMobile runs on an iPhone platform to support a mobile clinician.
Data Source	PeraTrend data comes from PeraServer	PeraWatch and PeraMobile data comes from PeraServer.	Same
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.	PeraWatch - a browser-based display configured for dedicated monitors providing an always-up, auto-refreshed display. PeraMobile – app-based display for use on mobile hand-held devices.	PeraWatch and PeraTrend both display data via a PC web browser. PeraMobile provides display on a mobile device (iPhone platform).
Ability to Trend	Yes	Yes	Same
Re-display of vital sign data	Re-displays vital sign data from EHR	Re-displays vital sign data from EHR	Same

	Primary Predicate	Subject Device	Discussion of Differences
Uses color to display information	*PeraTrend Array View*  *PeraTrend Single Graph View* 	*PeraWatch Array View*  *PeraWatch Single Graph View*  *PeraMobile Single Graph View* 	Use of color to indicate warning state and location of patient is the same across predicate and subject devices. The views are nearly identical across the predicate PeraTrend, and subject PeraWatch, and PeraMobile devices, with only small variations in the presentation of surrounding data.

Both the subject device and the predicate device rely on the same PeraServer system for data. PeraServer generates the RI score. The RI score algorithm has not changed since the previous submission, therefore the algorithm testing provided in the predicate submission (K172979) is relevant to this submission.

The timeliness of data and warnings in both subject and predicate devices has some dependency on the timeliness of data entry into the source (e.g. EHR systems). The extent and impact of delayed data entry on the generation of scores and warnings was explained in detail in the predicate device submission (K172959). As a result, the timeliness of warning generation and availability to the end user in the predicate device and the subject devices is identical.

Furthermore, the capability of the subject devices to provide a warning list in the case of PeraWatch, and an out-of-app warning notification in the case of PeraMobile, assists end users in having a more timely *awareness* of warnings than was the case in the predicate device, which required users to access and review patient RI graphs to determine if the patient was in a warning state.

5. CONCLUSION:

The subject PeraMobile and PeraWatch systems and the predicate PeraTrend 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 software testing demonstrate that the PeraMobile and PeraWatch systems perform in accordance with specifications and meets user needs and intended uses. Therefore, the PeraMobile and PeraWatch systems have been demonstrated to be substantially equivalent to the predicate PeraTrend.