January 22, 2026

Perin Health Devices, LLC
℅ Chandler Thames
Quality/Regulatory Consultant
Rook Quality Systems
1155 Mount Vernon Hwy
Suite 800
Dunwoody, Georgia 30338

Re: K252984
Trade/Device Name: Perin Health System (PHD80060-2)
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DQD, MHX, DQA, DXN, FLL, BZQ
Dated: December 19, 2025
Received: December 19, 2025

Dear Chandler Thames:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252984

Device Name

Perin Health System (PHD80060-2)

Indications for Use *(Describe)*

The Perin Health Platform is a wireless remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in healthcare and home settings for long-term monitoring. The Perin Health Patch can monitor auscultation data of heart and lung sounds, photoplethysmography waveforms (PPG), oxygen saturation (%SpO2), heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity detection (including step count), and posture (body position relative to gravity including fall).

The Perin Health System is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. In home-use environments, the Perin Health Platform is able to integrate with optional third-party devices for blood pressure, and weight data collection via the mobile application. The mobile application transmits data from the Health Patch and third party devices to the cloud and web-based portal for storage, analysis, and review by healthcare professionals. The Perin Health Platform can include the ability to notify healthcare professionals when physiological data falls outside set limits or manual trigger by the patient.

The device is intended to provide physiological information for non-critical, adult population.

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 for
Perin Health System

Submitter Perin Health Devices, LLC

Address 755 Research Parkway
Suite 530
Oklahoma City, OK 73104

Contact Ian McLane, *Chief Technology Officer*
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Email: ian.mclane@perinhealth.com

Date Prepared: January 22, 2026

Device Perin Health System

Trade Name: Perin Health System

Common Device Name: Transmitters and Receivers, Physiological Signal, Radio Frequency

Classification Product Code			
Regulation Medical Specialty	Regulation Classification	Product Code	Description
Cardiovascular	21 CFR 870.2910 Class II	DRG	Radiofrequency physiological signal transmitter and receiver
Subsequent Product Code			
Cardiovascular	21 CFR 870.1025 Class II	MHX	Monitor, physiological, patient (with arrhythmia detection or alarms)
Cardiovascular	21 CFR 870.1875 Class II	DQD	Stethoscope, electronic
Cardiovascular	21 CFR 870.2700 Class II	DQA	Oximeter
Cardiovascular	21 CFR 870.1130 Class II	DXN	System, measurement, blood-pressure, non-invasive
General Hospital	21 CFR 880.2910 Class II	FLL	Continuous measurement thermometer
Anesthesiology	21 CFR 868.2375 Class II	BZQ	Monitor, breathing frequency

Primary Predicate Device	UbiqVue 2A Multiparameter System
510(k) Number	K242018
Secondary Predicate Device	Alio Medical Remote Monitoring System
510(k) Number	K211365
Predicate for	Auscultation Sound Data
Reference Device	EKO CORE 500 Digital Stethoscope
510(k) Number	K230111
Reference for	Auscultation Sounds of the Heart and Lungs
Reference Device	Biobeat Platform-2 and BB-613WP Patch
510(k) Number	K222010
Reference for	Spot-Checking

Product Description

The Perin Health System is a wireless remote patient monitoring platform that enables healthcare professionals to perform spot-checking and retrospective monitoring of physiological data from adult patients. The Perin Health System is designed for use in hospitals, clinics, long-term care facilities, physician offices, and home environments.

The Perin Health System comprises the following components:

1. **Perin Health Patch wearable device**
2. **Perin Health Patient Mobile Application**
3. **Perin Health Cloud**
4. **Perin Health Provider Portal**
5. **Perin Health Inpatient Application**

1. The Perin Health Patch is a chest-worn wearable device that performs scheduled spot-check measurements of multiple physiological parameters. Unlike continuous monitoring systems, the Perin Health Patch captures measurements at predetermined intervals configured by healthcare providers based on clinical need.

   The device integrates six primary sensing modalities:

   - Auscultation (heart and lung sounds)
   - Electrocardiography (1-channel ECG)
   - Pulse oximetry via photoplethysmography (PPG)
   - Bioimpedance (BioZ) for respiratory monitoring
   - Temperature sensing (skin)
   - Motion and orientation detection via accelerometer

   The combination of these modalities in a small, low-power wearable form allows for the spot-checking of primary vital signs:

   - Heart rate and R-R intervals
   - Heart rate variability (HRV) parameters
   - ECG waveform data
   - Auscultation sound data (heart and lung sounds)
   - Respiratory rate
   - Pulse (PPG) waveform
   - Oxygen saturation (SpO2%)
   - Skin temperature
   - Fall detection events
   - Body posture
   - Activity level and step count

   The device adheres to the patient's upper left chest at the second intercostal space with a medical-grade long-term wear adhesive. The adhesive is placed on the patient-

facing side of the wearable, with cutouts for the sensors to make direct contact with the skin. The wearable device is lightweight and semi-flexible, allowing for the device to conform to the natural curvature of the chest. It is water resistant, allowing for bathing and normal activities while the patient is wearing the system.

The wearable communicates to the receiving unit (mobile phone) via an encrypted Bluetooth Low Energy connection. Measurements, all notifications and control commands, and software updates are transmitted over the BLE connection. The wearable uses Near Field Communication (NFC) to facilitate the Bluetooth pairing process with the mobile phone by simply having to tap their phone to the device to initiate a Bluetooth connection. The wearable device also contains on-board memory that can store over two weeks of spot-check data. When measurements are taken and no receiving unit is present, the wearable can store recordings in the onboard memory. Recordings are stored in a stack, such that at the next connection possibility between the wearable and the receiving unit, the most recent data will be transmitted first followed by other measurements in reverse chronological order.

Other key features of the wearable include:

- Customizable recording schedule set by the healthcare provider in their care program
- Replaceable battery
- Patient-triggered recordings via double-tap
- Signal quality indicators for measurement validation and identification of noisy measurements

2. The **Patient Mobile Application**, available on iOS or Android platforms, is intended exclusively for use in home environments by patients under healthcare provider supervision. The application serves as a data relay and display interface, allowing the patient to complete key tasks, including onboarding, device setup, device communication, and patient-reported data.

   The application serves as the primary interface between the Perin Health Patch and the cloud infrastructure, receiving spot-check measurements from the device and uploading them for provider review. The application establishes and manages secured BLE communication with the Health Patch. Given that the Health Patch operates on provider-configured recording schedules, the application manages data transfer in the background with minimal patient interaction required. When internet connectivity is

unavailable, the application stores measurements locally until transmission becomes possible. The system also manages firmware updates for the Perin Health Patch.

The application integrates with FDA-cleared third-party blood pressure cuff and scale using BLE and transfers the data to the Cloud System. Healthcare providers determine which patients require the additional third-party device monitoring as part of their individualized care programs. The system also allows users to optionally enter manual data for blood pressure and weight if no third-party device is connected.

Patients are able to review their historical measurement data taken throughout their monitoring program and their goals and thresholds set by their providers. The patient can view metrics assigned within their care program:

- Heart Rate and Heart Rate Variability
- Respiratory Rate
- Oxygen Saturation
- Step Count
- Temperature
- Blood Pressure
- Weight

Patients can also select audio segments captured by the device for playback (no visualization).

The application provides comprehensive patient engagement features. Patients can complete customized questionnaires with up to 20 questions in various formats, review educational content delivered through their care programs, and submit non-critical medical reports to their care team. The reporting feature includes anatomical body mapping for location-specific symptoms, severity scaling, and photo attachment capabilities. The application supports secure messaging with care providers, virtual appointment attendance with waiting room functionality, and comprehensive offline operation with automatic synchronization upon connectivity restoration.

3. The **Perin Health Cloud** infrastructure serves as the central hub for data management and processing. The cloud system receives encrypted spot-check data from relay systems and manages raw data processing (for Health Patch data only), storage, and retrieval of physiological measurements for retrospective clinical review.

Algorithms are run in the cloud to process measurements from the Health Patch and generate Signal Quality Index, Heart Rate, Heart Rate Variability, Respiratory Rate, Oxygen Saturation, and Posture.

The alert and notification system enables healthcare professionals to configure multi-level alerts based on clinical parameters, technical issues, or manual patient triggers. Clinical alerts are based on provider-configured thresholds that are set in during the enrollment of a patient in a care program. The system supports complex notification rules including threshold exceedances, percentage changes, trending patterns, and consecutive violations. Alerts are displayed to providers for the purpose of highlighting data during their retrospective review and are not intended to support real-time patient monitoring or urgent care provider action.

The cloud infrastructure includes comprehensive audit logging of all user actions, data access, and system events. The system provides API access for integration with electronic health records with HL7 v2.x, HL7 FHIR R4, and other standard protocols, enabling bidirectional data exchange with major EHR systems.

4. The web-based Provider Portal enables healthcare professionals to access and manage patient data and alert statuses remotely through any compatible web browser. Through the portal, providers can review spot-check measurements and historical trends, playback audio recordings of auscultation sounds captured by the Patch, configure individualized care programs, set measurement schedules and alert thresholds, and communicate with patients through various modalities.

   Through the portal, providers can review spot-check measurements with customizable vital sign charts displaying trends over days, weeks, or months. Advanced visualization includes waveform analysis for ECG and PPG signals, audio playback for auscultation recordings, and comprehensive annotation tools. The portal displays signal quality indicators and out-of-range values with appropriate visual highlighting based on configured thresholds. The portal also displays patient severity levels (Low/Medium/High) based on the NEWS2 scoring methodology. Additional clinical measures, such blood pressure and weight, that are manually input into the EHR can be read into the Perin Health System and viewed in the Provider Portal using the EHR interface.

   The system employs a structured care program architecture that ensures appropriate clinical oversight throughout the monitoring process. Healthcare organizations create standardized care program templates for common conditions. Individual providers can then select from these approved templates and customize them for specific patient

needs, prescribing the specific devices needed, measurement frequencies appropriate to the condition, and recording schedules tailored to clinical requirements.

The portal includes comprehensive communication capabilities supporting both patient and care team interactions. Providers can conduct virtual appointments with integrated video calling, AI-powered real-time transcription using AWS HealthScribe, and automated clinical note generation structured into standard sections. The messaging system supports secure text communication with file attachments, while the task management system enables care coordination across team members. Providers can create and deploy customized questionnaires with various response types and scoring algorithms, manage educational content delivery, and review patient-submitted reports with collaborative response capabilities.

Additional portal features include appointment scheduling with EHR integration, comprehensive alert management with acknowledgment workflows, administrative functions for user and device management, and organization hierarchy configuration. The portal provides detailed audit trails, performance analytics, and compliance reporting to support quality improvement initiatives.

5. The **Perin Health Inpatient Module** provides a monitoring dashboard for monitoring capabilities in healthcare facility environments through. The modules leverage the existing architectures for the Mobile Application and Provider Portal but offer unique interfaces for inpatient spot-check measurements.

   The web-based monitoring dashboard, a page accessible through the Provider Portal, displays vital signs for up to 50 concurrent patients in a grid layout. Each patient card shows the latest values for heart rate, respiratory rate, oxygen saturation, temperature, and device status, with automatic sorting by alert priority and visual indicators for threshold violations. The dashboard refreshes every second, updating as new spot-check recordings are captured from patients across the unit.

   The bedside Inpatient Application is built on top of the Android architecture of the Patient Mobile app and operates in kiosk mode. The Beside app only interfaces with the Perin Health Patch and relays information to the Cloud to provide clinicians with access to recent measurements in the Provider Portal Inpatient view. The application also maintains local data storage for backup operation and automatically synchronizes with the cloud upon connectivity restoration. Providers are unable to manually input clinical data (e.g., blood pressure measurements) directly into the bedside Inpatient Application but manual data input into the EHR can be read into and visualized in the Provider Portal over the EHR interface.

The Perin Health System supports monitoring in hospitals and out-of-hospital patient care settings where care is administered by healthcare professionals. Visual alarm indicators highlight parameter exceedances according to configured thresholds. High-priority alerts display prominently with appropriate color coding, though all clinical responses and acknowledgments must be performed through the Provider Portal to maintain proper documentation and workflow management.

The Perin Health System facilitates comprehensive spot-checking and retrospective monitoring across the continuum of care. Data flows from the wearable patch and third-party devices through the patient mobile application to the central cloud infrastructure, where processing algorithms derive clinical insights. Healthcare providers access this information through the web portal or inpatient displays for clinical review and analysis, enabling healthcare providers to track patient progress, adjust treatment plans based on measurements, and identify patients requiring intervention based on retrospective data trends.

Indications for Use

The Perin Health Platform is a wireless remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in healthcare and home settings for long-term monitoring. The Perin Health Patch can monitor auscultation data of heart and lung sounds, photoplethysmography waveforms (PPG), oxygen saturation (%SpO2), heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity detection (including step count), and posture (body position relative to gravity including fall).

The Perin Health System is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. In home-use environments, the Perin Health Platform is able to integrate with optional third-party devices for blood pressure, and weight data collection via the mobile application. The mobile application transmits data from the Health Patch and third party devices to the cloud and web-based portal for storage, analysis, and review by healthcare professionals. The Perin Health Platform can include the ability to notify healthcare professionals when physiological data falls outside set limits or manual trigger by the patient.

The device is intended to provide physiological information for non-critical, adult population.

Substantial Equivalence comparison (Subject Device and Predicate Devices)

	Perin Health System (Subject Device)	UbiqVue (Primary Predicate) – Used for ECG, Skin Temperature, Respiratory Rate, Oxygen Saturation	Alio (Secondary Predicate) – Used for Auscultation Sound Data
510k	K252984	K242018	K211365
Product code & regulation	DRG DQD, DQA, FLL, BZQ, DXN, MHX 870.2910	DRG DQA, FLL, MHX 870.2910	DRG DQD 870.2910
Intended Use	The Perin Health Platform is a wireless remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in healthcare and home settings for long-term monitoring. The Perin Health Patch can monitor auscultation data of heart and lung sounds, photoplethysmography waveforms (PPG), oxygen saturation (%SpO2), heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity detection (including step count), and posture (body position relative to gravity including fall). The Perin Health System is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. In home-use environments, the Perin Health Platform is able to integrate with optional third-party	The UbiqVue 2A Multiparameter System is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography (2-Channel ECG), heart Rate, SpO2%, respiration rate, pulse Rate, photoplethysmography waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart Rate variability (HRV) and blood Pressure (optional). Data is transmitted wirelessly near real time from UbiqVue 2A Wearable Biosensor and 3rd party device (for Blood Pressure only) to remote central server for display, storage, and analysis. The UbiqVue 2A Multiparameter System is intended for non-critical, adult population. The UbiqVue 2A Multiparameter System shall include the ability to notify healthcare professionals through alerts when physiological parameters fall outside the set limits, manual trigger by the patient and to display multiple patient's physiological data for remote monitoring at home and	The Alio Medical Remote Monitoring System is a wireless remote monitoring system intended for use by healthcare professionals to intermittently collect physiological data in home use settings. The data includes skin temperature, auscultation sound data and heart rate. Data is transmitted wirelessly from the SmartPatch wearable sensor to a web-based portal for the healthcare provider's (HCP) review. The Alio Medical RMS is intended for use on general care patients who are 18 years of age or older. The SmartPatch sensor is indicated to measure skin temperature and pulse rate where clinically indicated. The SmartPatch sensor is indicated to record and transmit auscultation sound data where clinically indicated. The device is not intended for use in critical care or other high-acuity

	Perin Health System (Subject Device)	UbiqVue (Primary Predicate) – Used for ECG, Skin Temperature, Respiratory Rate, Oxygen Saturation	Alio (Secondary Predicate) – Used for Auscultation Sound Data
	devices for blood pressure, and weight data collection via the mobile application. The mobile application transmits data from the Health Patch and third party devices to the cloud and web-based portal for storage, analysis, and review by healthcare professionals. The Perin Health Platform can include the ability to notify healthcare professionals when physiological data falls outside set limits or manual trigger by the patient. The device is intended to provide physiological information for non-critical, adult population.	with visual alarm for active monitoring at hospitals and out-of-hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.	environments. The Alio Medical RMS is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.
Intended Population	Non-critical, adult population, 22 years or older	Non-critical, adult population, 18 years or older	Non-critical, adult population, 18 years or older
Intended Use environment	Home & Healthcare settings	Home & Healthcare settings	Home setting only
Rx or OTC	Rx	Rx	Rx
Spot – Checking or Continuous	Spot-checking	Continuous	Intermittent
ECG	1-channel	2-channel	N/A
HR	20-200 bpm ± 3 BPM or 5%, whichever is greater	30-250BPM +- 3 BPM or 5% whichever is greater	30-200 BPM
RR Range and Accuracy	5-30 Breaths per Minutes ± 1 Breaths per Minute (Accuracy Root Mean	5-60 Breaths per Minute	N/A

	Perin Health System (Subject Device)	UbiqVue (Primary Predicate) – Used for ECG, Skin Temperature, Respiratory Rate, Oxygen Saturation	Alio (Secondary Predicate) – Used for Auscultation Sound Data
	Square (Arms) based on **bench testing**) ± 3 Breaths per Minute (Accuracy Root Mean Square (Arms) based on c**linical study**) Derived from Trans-thoracic Impedance (TTI) and ECG Derived Respiration (EDR) based on RS Amplitude	≤ 1 Breath per minute (Mean Absolute Error based on Simulation study) ≤ 3 Breaths per minute (Mean Absolute Error based on Clinical study) Trans-thoracic Impedance (TTI), ECG Derived Respiration (EDR) based on RS Amplitude & Respiratory Sinus arrhythmia (RSA) and Accelerometer data	
Skin Temperature	15 C - 50°C ± 0.3°C Resolution: 0.008°C Time response: 30 minutes Measurement mode: Direct ISO 80601-2-56	15C – 43C//59F-109.4F As per ASTM E1112-00	15 C - 50°C
Posture	Prone, supine, left lateral recumbent, right lateral recumbent, Fowler's, Trendelenburg, upright, leaning forward (> 80% average sensitivity and specificity, compared to visual)	Supine, Prone, Lying- Left/Right, Reclining, Reclining-Left/Right, Leaning Forward, Upright, Upside down	N/A
SpO2%	70% - 100% ± 3 % PPG, Signal Strength Indicator Chest Measurement site 530 nm (Green), 650 nm (Red), 940 nm (IR), Blue (475 nm)	0 to 100% ± 3 % (100 to 70%), Less than 70% unspecified PPG, Signal Strength Indicator Chest Measurement Site Spectral Sensor	N/A
R-R interval	Sinus Heart Rate	Beat Classification Sinus Heart Rate	N/A
Heart Rate Variability (HRV)	SDNN (short), RMSSD, TINN, pNN50, VLF Band, LF Band, HF Band	SDNN, SDANN, ASDNN, RMSSD, VLF Band, LF Band, HF Band	N/A
Body Motion	Active or sedentary (> 90% sensitivity and specificity)	No Body Motion, Mild Body Motion, Moderate Body Motion,	N/A

	Perin Health System (Subject Device)	UbiqVue (Primary Predicate) – Used for ECG, Skin Temperature, Respiratory Rate, Oxygen Saturation	Alio (Secondary Predicate) – Used for Auscultation Sound Data
		Severe Body Motion	
Fall Detection	Fall or no fall (> 80% sensitivity and specificity)	N/A	N/A
Step Count	< 5% Absolute Error Compared to Manual Count for speeds of at least 2 miles per hour Compliance: ANSI/CTA-2056-A	N/A	N/A
Emitted light peak wavelength	530 nm (Green), 650 nm (Red), 940 nm (IR), Blue (475 nm)	N/A	530 nm (Green), 650 nm (Red), 940 nm (IR)
Sound Data	Heart Lungs	N/A	Heart Lungs Bowel Arteries Veins
Sound Amplification	Yes	N/A	Yes
Record and Playback Sound	Yes (Playback via Provider Portal and Mobile Application)	N/A	Yes (Playback via Clinician Portal)
Sensor Type	Thermistor Electrocardiogram (ECG) Contact Acoustic sensor Bioimpedance PPG Accelerometer	Thermistor Electrocardiogram (ECG) - Bioimpedance PPG Accelerometer	Thermistor - Microphone - PPG Accelerometer
Single Use	Multiple Use by Single User	Yes	Yes
Wear Life	360 hours	120 hours	120 Hours
Dimension	80 mm x 45 mm x 14 mm	116mm x 91mm x17 mm	150mm x 94mm x 36mm
Weight	19 g	35 g	Unknown
ECG Electrode distance	Single lead 60mm electrode distance	90.0 mm 73.0 mm	N/A
Location on body	Upper chest, below the left collarbone	Upper Center Chest or Upper Left Chest	Unknown
Data can be transferred and temporarily stored	Yes	Yes	Unknown
Battery	LiMnO2 (Primary)	LiMnO2 (Primary)	Li-ion

	Perin Health System (Subject Device)	UbiqVue (Primary Predicate) – Used for ECG, Skin Temperature, Respiratory Rate, Oxygen Saturation	Alio (Secondary Predicate) – Used for Auscultation Sound Data
Applied part category	BF	CF	Unknown
Defibrillation proof	Yes	Yes	Unknown
HF Surgical equipment compatibility	No	Yes	Unknown
Communication protocol	BLE 5.4	WLAN (802.11b), BLE 5.2	BLE
Wireless Radio Frequency	2.4 - 2.5 GHz	2.4 - 2.4835 GHz	2.4 - 2.5 GHz
Communication Security	AES-CTR 256	WPA2-PSK /CCMP AES-CCM 128	Unknown
Authentication from server	Yes	Yes	Unknown
Data transferred to server	Yes	Yes	Unknown
Data buffered if there is no connection with server	Yes	Yes	Unknown
GUI for patient admission (only for single patient relay)	Yes	Yes	Unknown
GUI for PPG signal quality (only for single patient relay)	Yes	Yes	Unknown
Secure Server	Data is stored for access by the Perin Health Mobile Application and Provider Portal.	Data is stored for access by Active Monitoring Portal & any 3rd party server (through API)	Unknown
Programmable Alert Notification & Configurable	Yes (Clinical, Technical, Manual)	Yes (Clinical, Technical, Manual)	Unknown
Early Warning Score (NEWS2)	Yes	Yes	Unknown
Multi-patient tile view	Yes	Yes	Unknown

	Perin Health System (Subject Device)	UbiqVue (Primary Predicate) – Used for ECG, Skin Temperature, Respiratory Rate, Oxygen Saturation	Alio (Secondary Predicate) – Used for Auscultation Sound Data
Single patient zoom view	Yes	Yes	Unknown
Visual alarm indication	Yes	Yes	Unknown

Differences Discussion:

- The Subject device has an additional physiological monitoring capability via 3rd party device integration, weight data. However, the performance of this parameter is verified and validated, and the 3rd party device (Transtek TeleRPM GBS2012-B) is a Class I, 510(k) exempt device. Hence, this additional parameter does not affect the intended use of the Subject device.
- The Subject Device does not claim to measure body temperature as the Primary Predicate Device. This does not impact the indications for use nor substantial equivalence.
- The Subject device is intended to perform spot-checking monitoring compared to continuous monitoring of the Primary Predicate device, as this is a narrower scope of the Primary Predicate Device, this does not impact the indications for use nor substantial equivalence.

Comparison with Reference Devices

The EKO Core 500 Digital Stethoscope is used as a reference for the auscultation sounds of the heart and lungs performed by the Perin Health System.

	Perin Health System (Subject Device)	EKO CORE 500 Digital Stethoscope (Reference Device)
510k	K252984	K230111
Product code & regulation	DRG DQD, DQA, FLL, BZQ 870.2910	DQD DPS 870.1875
Intended Use	The Perin Health Platform is a wireless remote monitoring system intended for use by healthcare	The CORE 500 Digital Stethoscope is intended to be used by clinicians to electronically amplify, The CORE

	Perin Health System (Subject Device)	EKO CORE 500 Digital Stethoscope (Reference Device)
	professionals for spot check collection of physiological data in healthcare and home settings for long-term monitoring. The Perin Health Patch can monitor auscultation data of heart and lung sounds, photoplethysmography waveforms (PPG), oxygen saturation (%SpO2), heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity detection (including step count), and posture (body position relative to gravity including fall). The Perin Health System is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. In home-use environments, the Perin Health Platform is able to integrate with optional third-party devices for blood pressure, and weight data collection via the mobile application. The mobile application transmits data from the Health Patch and third party devices to the cloud and web-based portal for storage, analysis, and review by healthcare professionals. The Perin Health Platform can include the ability to notify healthcare professionals when physiological	500 Digital Stethoscope is intended to be used by clinicians to electronically amplify, filter, and transfer body sounds and three lead electrocardiogram (ECG) waveforms. The CORE 500 Digital Stethoscope also displays ECG waveforms and heart rate on the display and accompanying mobile application (when prescribed or used under the care of a clinician). The data offered by the device is only significant when used in conjunction with clinician evaluation as well as consideration of other relevant patient data.

	Perin Health System (Subject Device)	EKO CORE 500 Digital Stethoscope (Reference Device)
	data falls outside set limits or manual trigger by the patient. The device is intended to provide physiological information for non-critical, adult population.	
Single Use	Multiple Use by Single User	Unknown
Wear Life	360 hours	60 hours
Intended Population	Non-critical, adult population, 22 years or older	Adults and pediatrics
Intended Use environment	Home & Healthcare settings	Healthcare
Rx or OTC	Rx	Rx
Sensor Type	Contact Acoustic Sensor	Contact Acoustic Sensor
Sound Amplification	Yes	Yes
Audio Frequency Range	40 – 2000 Hz	20 – 2000 Hz
Software Interface	Mobile Application Web Portal	Mobile Application

The Biobeat Platform-2 and BB-613WP Patch (K222010) is used as a reference for spot-checking performed by the Perin Health System.

	Perin Health System (Subject Device)	Biobeat Platform-2 and BB-613WP Patch (Reference Device)
510k	K252984	K222010
Product code & regulation	DRG DQD, DQA, FLL, BZQ, DXN, MHX 870.2910	DQA BZQ, DRG, DXG, DXN, FLL 870.2700
Intended Use	The Perin Health Platform is a wireless remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in healthcare and home settings for long-term monitoring. The Perin Health Patch can monitor auscultation data of heart and lung sounds, photoplethysmography waveforms (PPG), oxygen saturation (%SpO2), heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, skin temperature, activity detection (including step count), and posture (body position relative to gravity including fall). The Perin Health System is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. In home-use environments, the Perin Health Platform is able to integrate	The Biobeat Platform-2 is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO2), pulse rate, blood pressure, respiration rate (RRp), hemodynamic parameters (stroke volume, cardiac output), and body temperature. The Biobeat Platform-2 tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor.

	Perin Health System (Subject Device)	Biobeat Platform-2 and BB-613WP Patch (Reference Device)
	with optional third-party devices for blood pressure, and weight data collection via the mobile application. The mobile application transmits data from the Health Patch and third party devices to the cloud and web-based portal for storage, analysis, and review by healthcare professionals. The Perin Health Platform can include the ability to notify healthcare professionals when physiological data falls outside set limits or manual trigger by the patient. The device is intended to provide physiological information for non-critical, adult population.	The Biobeat Platform-2 is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care, and at home. The data from the Biobeat Platform-2 are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.
Intended Population	Non-critical, adult population, 22 years or older	Non-critical, adult population, 18 years or older
Intended Use environment	Home & Healthcare settings	Home & Healthcare settings
Rx or OTC	Rx	Rx
Spot – Checking or Continuous	Spot-checking	Spot-checking

Discussion of technological differences:

- The Subject device has an additional physiological monitoring capability, weight data, via integration with a third-party device (Class I, 510(k) exempt, Transtek TeleRPM GBS2012-B). The weight data integration has been verified and validated to

perform as intended. Additionally, weight data is at the discretion of the treating healthcare provider, based on clinical need. Since this parameter is acquired through a low-risk technology, when deemed appropriate by a physician, for supplemental patient information, there is no introduction of additional risk.

- The Subject device is intended to perform spot-checking monitoring compared to continuous monitoring of the Primary Predicate device, as this is a narrower scope of the Primary Predicate Device, this does not add any additional risk.
- The Subject Device utilizes one ECG channel whereas the Primary Predicate Device utilizes two. As this is a narrower scope of the Primary Predicate Device, this does not add any additional risk.
- The Subject Device utilizes a contact acoustic sensor to measure auscultation data of the heart and lungs. The Secondary Predicate Device utilizes a microphone to measure auscultation data. However, the Reference Device for Auscultation Data also utilizes a contact acoustic sensor to perform this measurement, and thus, there is no introduction of additional risk.
- The Subject device also allows playback of auscultation sound data via the Provider Portal and the Mobile Application (patient). In contrast, the Secondary Predicate Device only allows playback via the clinician portal. The auscultation feature of the Perin Health System is solely indicated for recording and playback of body sounds to support clinical assessment, including interpretation and findings, by qualified healthcare professionals. However, patients using the Perin Health System are able to confirm they were able to take a recording via the Mobile Application playback option. Thus, this is a risk mitigation, ensuring patients can verify a successful recording, and it does not add additional risk.
- The predicate device, the UbiqVue Multiparameter 2A, utilizes wet (hydrogel) electrodes for biopotential signal acquisition, whereas the subject device employs dry electrodes. Although the electrode technology differs, the subject device has been demonstrated to perform equivalently to standard wet electrodes. Bench and performance testing, including verification against ANSI/AAMI EC12, confirmed that the dry electrodes meet the same safety and performance requirements as hydrogel electrodes. Accordingly, this difference in electrode technology does not raise new questions of safety or effectiveness.

Summary of Performance Testing

Verification & Validation activities were performed on Perin Health System to demonstrate substantial equivalence to the predicate device:

- Biocompatibility testing of In-vitro cytotoxicity, skin irritation and skin sensitization were conducted on Perin Health System, according to ISO 10993-1: 2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. Tests were performed in accordance with ISO 10993-5:2009, ISO 10993-10:2021, and ISO 10993-23:2021.
- Electrical Safety and electromagnetic compatibility testing were conducted on the Perin Health System for compliance with IEC 60601-1(Ed.3.2), IEC 60601-1-2 (Ed. 4.1) and IEC 60601-1- 11(Ed. 2.1).
- The Skin temperature accuracy performance of the Perin Health System was verified by using bench testing, as per ISO 80601-2-56:2017(E).
- ECG, Heart Rate, R-R Interval, and Heart Rate Variability performance testing was performed on the Perin Health System in compliance with ANSI/AAMI/IEC 60601-2-27:2011, ANSI/AAMI/IEC 60601-2-47:2012.
- Auscultation data of heart and lung sounds has been verified by using bench testing in accordance with acceptance criteria.
- Defibrillation proof testing was performed on the Perin Health System for compliance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020.
- Body Motion, Fall Detection, and Posture performance of the Perin Health System were verified by using bench testing as per the acceptance criteria.
- Step Count performance of the Perin Health System was verified via bench testing as per ANSI/CTA-2056-A.
- The Alert system & Visual alarm display on the Perin Health System was verified for compliance with IEC 60601-1-8 (Ed. 2.2).
- Usability study was conducted on the Perin Health System for compliance with IEC 60601-1-6 (Ed. 3.2) and “USFDA Guidance- Applying Human Factors and Usability Engineering to Medical Devices.”
- Wireless performance & coexistence testing conducted as per ANSI/IEEE C63.27:2017: American National Standard for Evaluation of Wireless coexistence on the Perin Health System.
- Software in the Perin Health System was designed, documented, verified & validated as per the IEC 62304: Medical device Software - Software Life Cycle Process and USFDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Device. The Software for this device is determined as Class C and Enhanced Documentation Level.

- Software in the Perin Health System was securely designed, documented, verified & validated as per the USFDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.
- Shelf-life testing was conducted and verified on the Perin Health Patch, as per the acceptance criteria.
- Packaging testing conducted on the packaged Perin Health Patch as per ISTA 6.

Summary of Clinical Testing

Clinical validation activities were performed on Perin Health System to demonstrate substantial equivalence to the predicate device:

- The Perin Health System and Patch were verified & validated for no motion accuracy in compliance with ISO 80601-2-61(Ed. 2.0) including clinical validation to determine the accuracy of SpO2% in induced hypoxia studies in the range of 70% to 100% SpO2 against arterial blood samples analyzed by a laboratory co-oximeter.
    - 12 healthy adults (5 female, 7 male), ages 24-42, Monk scale assessment across 5 anatomical sites (1 B, 2 C, 2 D, 3 E, 2 G, 2 H).
    - The overall measured Arms in the range of 70 to 100% SpO_2 was 3.3%, with Arms of 3.5 for 67% to <80%, 3.1 for 80% to <90%, and 3.3 for 90% to 100%.
- The Respiratory Rate accuracy performance of the Perin Health System was verified by using bench testing and through clinical validation against the gold standard, manually counted end-tidal CO_2.
    - The demographics of the analyzed population were 17 males and 18 females (age: 24-72 years, weight: 111-390 lbs, height: 60-75 inches, BMI: 18-50). 1 American Indian/Alaska Native, 2 Asian, 8 Black/African-American, 23 White, and 1 other, with 8 participants of Hispanic/Latino ethnicity and 27 of Non-Hispanic/Non-Latino ethnicity were completed.
    - After baseline data was collected at the participant's natural respiratory rate, a range of stable respiratory rates (approx. 5, 10, 15, 20, 25, and 30 breaths per minute) were elicited from each volunteer.
    - Subgroup analysis was conducted for sex, comorbidities (asthma, diabetes, COPD, smoker, hypertension, congestive heart failure), BMI, age, and skin tone.
    - The accuracy root mean square (Arms) for 259 points was 1.7 breaths per minute, with all subgroups exhibiting Arms between 0.5 and 2.8.
    - The mean absolute error (MAE) for 259 points was 0.8 breaths per minute, with all subgroups exhibiting MAE between 0.4 and 1.3.
- ECG, Heart Rate, R-R Interval, and Heart Rate Variability performance testing was performed on the Perin Health System through clinical validation against a standard Holter monitor.

  - 243 participants were analyzed for ECG, HR, and HRV performance. Participants were enrolled from a diverse composition of gender (51.4% female/48.6% male), race (Asian 17.7%, Black/African American 15.2%, Hispanic or Latino 16.9%, White 39.9%, Other or Multiple 9.5%), age (22-90 with 32.1% ≥ 60 years), and a mix of healthy controls (50.78%) and patients with chronic conditions (hypertension, cardiovascular diseases, COPD, diabetes, and arrhythmias).
  - The ECG performance validation demonstrated high levels of agreement between the Perin Health patch and the reference Holter monitor across all evaluated parameters (timing intervals, SNR, morphological features) and for all demographic and clinical subgroups.
- Wear-life performance of the Perin Health Patch was verified & validated for compliance via internal clinical wear life evaluation to confirm sustained adhesion to the body for 360 hours.
  - 26 participants were enrolled across 3 clinical sites, with a balanced sex distribution, 30% aged ≥ 60 years, 30% with BMI ≥ 30, and including healthy controls and patients with documented arrhythmias.
  - The system demonstrated stable performance across all evaluated parameters (timing intervals, SNR, morphological features) and for all demographic and clinical subgroups.

Conclusion

The Perin Health System is substantially equivalent in indications for use & intended use to the legally marketed Predicate Device(s) & Reference Device(s). Minor differences between the Perin Health System and the Predicate & Reference devices have no significant effect on safety or effectiveness, as established through various performance tests. Thus, the proposed device/system is substantially equivalent to the legally marketed predicate & reference devices.