June 6, 2025

Empatica S.r.l.
Alberto Poli
Director, Quality & Regulatory Compliance
Via Stendhal, 36
Milan, 20144
Italy

Re: K242737
Trade/Device Name: Empatica Health Monitoring Platform; EmbracePlus; Empatica Care; Care Portal
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, BZQ, DRG, FLL, LEL, GZO
Dated: May 6, 2025
Received: May 6, 2025

Dear Alberto Poli:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242737

Device Name

Empatica Health Monitoring Platform;
EmbracePlus;
Empatica Care;
Care Portal

Indications for Use *(Describe)*

The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers for retrospective remote monitoring of physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments. As the platform does not provide real-time alerts related to variation of physiologic parameters, users should use professional judgment in assessing patient clinical stability and the appropriateness of using a monitoring platform designed for retrospective review.

The device is intended for continuous data collection supporting intermittent retrospective review of the following physiological parameters:
• Pulse Rate,
• Blood Oxygen Saturation under no-motion conditions,
• Respiratory Rate under no motion conditions,
• Peripheral Skin Temperature,
• Electrodermal Activity,
• Activity associated with movement during sleep

The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion.

The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature at the wrist is clinically indicated.

The Empatica Health Monitoring Platform is not intended for Respiratory Rate monitoring in motion conditions. This device does not detect apnea and should not be used for detecting or monitoring cessation of breathing.

The Empatica Health Monitoring Platform is not intended for Pulse Rate monitoring in patients with chronic cardiac arrhythmias, including atrial fibrillation and atrial/ventricular bigeminy and trigeminy, and is not intended to diagnose or analyze cardiac arrhythmias. The Empatica Health Monitoring Platform is not a substitute for an ECG monitor, and should not be used as the sole basis for clinical decision-making.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Empatica Srl
Traditional 510(k)

Empatica Health Monitoring Platform

510(k) Summary

I. SUBMITTER

Company Name	Empatica Srl
Establishment Registration Number	3012933969
Contact Person	Alberto Poli, Director, Quality & Regulatory Compliance
Contact Person email	apo@empatica.com
Address	Via Stendhal, 36 - 20144, Milan, Italy
Telephone Number	+39 02 36165068
Date prepared	September 10, 2024

II. DEVICE

Trade/Proprietary Name: Empatica Health Monitoring Platform
Common/Usual Name: Remote Patient Monitoring System

Primary Product Code:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
870.2300	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	Class II	MWI	Cardiovascular

Secondary Product Codes:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
870.2700	Oximeter	Class II	DQA	Cardiovascular
868.2375	Monitor, Breathing Frequency	Class II	BZQ	Anesthesiology
870.2910	Transmitters and Receivers, Physiological Signal, Radiofrequency	Class II	DRG	Cardiovascular
882.5050	Device, Sleep Assessment	Class II	LEL	Neurology
882.1540	Galvanic skin response measurement device	Class II	GZO	Neurology
880.2910	Thermometer, Electronic, Clinical	Class II	FLL	General Hospital

III. PREDICATE DEVICES

Predicate Device	Name	Submitter	Product Code(s)	510(k) Number
Primary	Empatica Health Monitoring Platform	Empatica S.r.l.	MWI DQA BZQ DRG LEL GZO FLL	K230457

The predicate has not been subject to a design-related recall.

IV. REFERENCE DEVICE

No reference device has been used for this submission

V. DEVICE DESCRIPTION

The Empatica Health Monitoring Platform is a wearable device and software platform composed by:

- A wearable medical device called EmbracePlus,
- A mobile application running on smartphones called "Care App",
- A cloud-based software platform named "Care Portal".

The EmbracePlus is worn on the user's wrist and continuously collects raw data via specific sensors. These data are wirelessly transmitted via Bluetooth Low Energy to a paired mobile device where the Care App is up and running. The data received are analyzed by one of the Care App software modules, EmpaDSP, which computes the user physiological parameters. Based on the version of the Care App installed, the user can visualize a subset of these physiological parameters. The Care App is also responsible for transmitting, over cellular or Wi-Fi connection sensors' raw data, device information, Care App-specific information, and computed physiological parameters to the Empatica Cloud. On the Empatica Cloud, these data are stored, further analyzed, and accessible by healthcare providers or researchers via a specific cloud-based software called Care Portal.

The Empatica Health Monitoring Platform is intended for retrospective remote monitoring of physiological parameters in ambulatory adults in home-healthcare environments. It is designed to continuously collect data to support intermittent monitoring of the following physiological parameters and digital biomarkers by trained healthcare professionals or researchers: Pulse Rate (PR), Respiratory Rate (RR), blood oxygen saturation (SpO_2), peripheral skin temperature (TEMP), and electrodermal activity (EDA). Activity sensors are used to detect sleep periods and to monitor the activity associated with movement during sleep.

VI. INDICATION FOR USE

The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers for retrospective remote monitoring of physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments. As the platform does not provide real-time alerts related to variation of physiologic parameters, users should use professional judgment in assessing patient clinical stability and the appropriateness of using a monitoring platform designed for retrospective review.

The device is intended for continuous data collection supporting intermittent retrospective review of the following physiological parameters:

- Pulse Rate,
- Blood Oxygen Saturation under no-motion conditions,
- Respiratory Rate under no motion conditions,
- Peripheral Skin Temperature,
- Electrodermal Activity,
- Activity associated with movement during sleep

The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion.

The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature at the wrist is clinically indicated.

The Empatica Health Monitoring Platform is not intended for Respiratory Rate monitoring in motion conditions. This device does not detect apnea and should not be used for detecting or monitoring cessation of breathing.

The Empatica Health Monitoring Platform is not intended for Pulse Rate monitoring in patients with chronic cardiac arrhythmias, including atrial fibrillation and atrial/ventricular bigeminy and trigeminy, and is not intended to diagnose or analyze cardiac arrhythmias. The Empatica Health Monitoring Platform is not a substitute for an ECG monitor, and should not be used as the sole basis for clinical decision-making.

I. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The application Empatica Health Monitoring Platform is substantially equivalent to the identified predicate devices. The devices have similar Indications for Use, features, technology, and accuracy.

Features	Empatica Health Monitoring Platform (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
Common Name	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	N/A
Device Manufacturer	Empatica S.r.l.	Empatica S.r.l.	N/A
Device Classification	II	II	N/A
510(k) number	N/A	K230457	N/A
Primary Product Code	MWI	MWI	N/A
Secondary Product Code	DQA, BZQ, DRG, GZO, LEL, FLL	DQA, BZQ, DRG, GZO, LEL, FLL	N/A
Intended Use/Indications for Use	The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers for retrospective remote monitoring of physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments. As the platform does not provide real-time alerts related to variation of physiologic parameters, users should use professional judgment in assessing patient clinical stability and the appropriateness of using a monitoring platform designed for retrospective review.	The Empatica Health Monitoring Platform is a wearable device and paired mobile and cloud-based software platform intended to be used by trained healthcare professionals or researchers for retrospective remote monitoring of physiologic parameters in ambulatory individuals 18 years of age and older in home-healthcare environments. As the platform does not provide real-time alerts related to variation of physiologic parameters, users should use professional judgment in assessing patient clinical stability and the appropriateness of using a monitoring platform designed for retrospective review.	The subject device and the predicate are identical

Features	Empatica Health Monitoring Platform (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
	The device is intended for continuous data collection supporting intermittent retrospective review of the following physiological parameters: ● Pulse Rate, ● Blood Oxygen Saturation under no-motion conditions, ● Respiratory Rate under no motion conditions, ● Peripheral Skin Temperature, ● Electrodermal Activity, ● Activity associated with movement during sleep The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable. The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion. The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature at the wrist is clinically indicated. The Empatica Health Monitoring Platform is not intended for Respiratory Rate monitoring in motion conditions. This device does not detect apnea and should not be used for detecting or monitoring cessation of breathing. The Empatica Health Monitoring Platform is not intended for Pulse Rate monitoring in patients with	The device is intended for continuous data collection supporting intermittent retrospective review of the following physiological parameters: ● Pulse Rate, ● Blood Oxygen Saturation under no-motion conditions, ● Respiratory Rate under no motion conditions, ● Peripheral Skin Temperature, ● Electrodermal Activity, ● Activity associated with movement during sleep The Empatica Health Monitoring Platform can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable. The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion. The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature at the wrist is clinically indicated. The Empatica Health Monitoring Platform is not intended for Respiratory Rate monitoring in motion conditions. This device does not detect apnea and should not be used for detecting or monitoring cessation of breathing.	

Features	Empatica Health Monitoring Platform (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
	chronic cardiac arrhythmias, including atrial fibrillation and atrial/ventricular bigeminy and trigeminy, and is not intended to diagnose or analyze cardiac arrhythmias. The Empatica Health Monitoring Platform is not a substitute for an ECG monitor, and should not be used as the sole basis for clinical decision-making.	The Empatica Health Monitoring Platform is not intended for Pulse Rate monitoring in patients with chronic cardiac arrhythmias, including atrial fibrillation and atrial/ventricular bigeminy and trigeminy, and is not intended to diagnose or analyze cardiac arrhythmias. The Empatica Health Monitoring Platform is not a substitute for an ECG monitor, and should not be used as the sole basis for clinical decision-making.	
Target Population	Adult	Adult	The subject device and the predicate are identical
Anatomical Site	Wrist	Wrist	The subject device and the predicate are identical
Over the Counter or Rx	Rx	Rx	The subject device and the predicate are identical
Environment	Home	Home	The subject device and the predicate are identical
Alarms	No	No	The subject device and the predicate are identical
User Interface	Device screen, Mobile device application, and cloud software platform	Device screen, Mobile device application, and cloud software platform	The subject device and the predicate are identical
Energy Source	Battery	Battery	The subject device and the predicate are identical
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	The subject device and the predicate are identical
Wireless Communication Interface	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	The subject device and the predicate are identical
Patient contacting materials	Compliant to ISO 10993-1	Compliant to ISO 10993-1	The subject device and the predicate are identical

Features	Empatica Health Monitoring Platform (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
Predetermined Change Control Plan	PCCP included in the submission	No PCCP included in the submission.	The subject device is substantially equivalent to the predicate device, other than the implementation of an authorized Predetermined Change Control Plan (PCCP) specific to a subcomponent of the SpO_2 algorithm

Technical and Performance Information for Pulse Rate			
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
Technology	PR measured by analyzing cyclic variations in the reflectance of certain LED frequencies in a photoplethysmogram design. The diodes are mounted in the device such that they are in contact with the skin.	PR measured by analyzing cyclic variations in the reflectance of certain LED frequencies in a photoplethysmogram design. The diodes are mounted in the device such that they are in contact with the skin.	The subject device and the predicate are identical
Range	24 – 240 beats per minute (bpm)	24 – 240 beats per minute (bpm)	The subject device and the predicate are identical
Resolution	1 bpm	1 bpm	The subject device and the predicates are identical
Accuracy	(no-motion) 3 bpm A_{rms} (motion) 5 bpm A_{rms}	(no-motion) 3 bpm A_{rms} (motion) 5 bpm A_{rms}	The subject device and the predicate are identical

The Empatica Health Monitoring Platform version presented in this 510(k) submission has introduced no changes to the computation of Pulse Rate compared with the cleared version. No additional clinical data or documentation has been attached to these 510(k) submissions.

Technical and Performance Information for Respiratory Rate			
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Empatica Health Monitoring Platform (K221282)**	**Analysis of differences**
Technology	Respiration rate (RR) data is continuously collected by analyzing cyclic variations in the photoplethysmogram. The diodes are mounted in the device such that they are in contact with the skin	Respiration rate (RR) data is continuously collected by analyzing cyclic variations in the photoplethysmogram. The diodes are mounted in the device such that they are in contact with the skin	The subject device and the predicate are identical
Range	6 – 40 breaths per minute (brpm)	6 – 40 breaths per minute (brpm)	The subject device and the predicate are identical
Resolution	1 brpm	1 brpm	The subject device and the predicate are identical
Accuracy	3 brpm A_{rms}	3 brpm A_{rms}	The subject device and the predicate are identical

The Empatica Health Monitoring Platform version presented in this 510(k) submission has introduced no changes to the computation of Respiratory Rate compared with the cleared version. No additional clinical data or documentation has been attached to these 510(k) submissions.

Technical and Performance Information for Blood Oxygen Saturation			
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
Technology	SpO2 relies on the principle that hemoglobin at different oxygenation states absorbs light differently based upon the wavelength of light.	SpO2 relies on the principle that hemoglobin at different oxygenation states absorbs light differently based upon the wavelength of light.	The subject device and the predicate are identical
SpO_2 Range	70-100%	70-100%	The subject device and the predicates are identical
SpO_2 Resolution	1%	1%	The subject device and the predicates are identical
SpO_2 Accuracy	3% A_{rms}	3% A_{rms}	The subject device and the predicate are identical

The Empatica Health Monitoring Platform version presented in this 510(k) submission has introduced no changes to the computation of blood oxygen saturation (SpO2) compared with the cleared version. No additional clinical data or documentation have been attached to these 510(k) submissions.

Technical and Performance Information for Temperature			
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Empatica Health Monitoring Platform (K221282)**	**Analysis of differences**
Technology	high-precision temperature sensor	high-precision temperature sensor	The subject device and the predicate are identical
Temperature Range	0°C to 50°C	0°C to 50°C	The subject device and the predicate are identical
Temperature Resolution	0.1°C	0.1°C	The subject device and the predicate are identical
Temperature Accuracy	± 0.1°C within 30.0°C - 45.0°C range	± 0.1°C within 30.0°C - 45.0°C range	The subject device and the predicate are identical

The Empatica Health Monitoring Platform version presented in this 510(k) submission has introduced no changes to the computation of Peripheral Skin Temperature (TEMP) compared with the cleared version. No additional bench test and validation data or documentation have been attached to these 510(k) submissions.

Technical and Performance Information for Electrodermal Activity			
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Empatica Health Monitoring Platform (K221282)**	**Analysis of differences**
Technology	EDA is measured by analyzing detected changes in the conductivity of the superficial layers of the skin.	EDA is measured by analyzing detected changes in the conductivity of the superficial layers of the skin.	The subject device and the predicate are identical
EDA Range	0.01 µS – 100 µS	0.01 µS – 100 µS	The subject device and the predicate are identical
EDA Resolution	1 digit ~ 55 pS	1 digit ~ 55 pS	The subject device and the predicate are identical

The Empatica Health Monitoring Platform version presented in this 510(k) submission has introduced no changes to the computation of EDA compared with the cleared version. No additional bench test and validation data or documentation have been attached to these 510(k) submissions.

Technical and Performance Information for Activity and Sleep			
Features	**Empatica Health Monitoring Platform (Subject Device)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
Technology	Accelerometer	Accelerometer	The subject device and the predicate are identical
Accelerometer Type	Microelectromechanical system (MEMS)-based integrated circuit	Microelectromechanical system (MEMS)-based integrated circuit	The subject device and the predicate are identical
Accelerometer Sampling Rate	Digital method, 26 Hz – 208 Hz	Digital method, 26 Hz – 208 Hz	The subject device and the predicate are identical
Accelerometer Dynamic Range	± 16 g	± 16 g	The subject device and the predicate are identical
Accelerometer Sensitivity	0.488 milli-g per Least Significant Bit	0.488 milli-g per Least Significant Bit	The subject device and the predicate are identical

The Empatica Health Monitoring Platform version presented in this 510(k) submission has introduced no changes to the computation of ActivityCounts and activity during sleep (ACT and SLEEP) compared with the cleared version. No additional bench test and validation data or documentation have been attached to this 510(k) submission.

The technological characteristics of the subject device are identical to the predicate device, other than the implementation of a Predetermined Change Control Plan (PCCP) that specifies anticipated modification to the EHMP and the test methods that will be utilized to implement those modifications in a controlled manner such that the device is as safe and as effective as the predicate.

II. PREDETERMINED CHANGE CONTROL PLAN

A PCCP for the Empatica Health Monitoring Platform is included as part of this submission to outline the rationale, processes and criteria for managing future SpO_2 algorithm modifications. This plan details the steps for evaluating, implementing, and documenting changes to ensure continued compliance and performance. The table below reports a summary of the proposed modification, with a description outlining the rationale and the implementation.

Modification	Description
The existing SpO_2 Quality Indicator (QI) - which determines the quality of input photoplethysmography (PPG) data to decide whether a SpO2 output should be exposed to the user - will be updated by replacing the rule-based algorithm with a Machine Learning-based algorithm	The modification will be a one-time only change, implemented by ● Keeping the same input PPG signals and the same type of binary output. ● Enhancing the development dataset with new samples to guarantee the generalizability of the new ML-based algorithm, performing feature extraction and engineering on window lengths spanning a 10-30-second range. ● developing an ML classifier for PPG data quality assessment, prioritizing model interpretability and explainability.

Testing methods will include both bench testing and clinical testing, and will require the performance of the modified SpO_2 algorithm to be non-inferior to the original, FDA-cleared algorithm. The testing methods and acceptance criteria for the performance validation are summarized in the table below. In addition, all software verification tests linked to requirements and specifications must pass for the modification to be considered valid and implemented in the product.

Testing methods	Acceptance Criteria
Bench testing conducted using a functional tester to simulate a range of representative signal quality issues	The Sensitivity, Specificity, and False Discovery Rate of the modified SpO_2 QI algorithm in discriminating low-quality and high-quality data are non-inferior to the SpO_2 QI in the FDA-cleared SpO_2 algorithm
Clinical testing conducted in accordance with ISO 80601-2-61 Medical electrical equipment - Part 261: Particular requirements for basic safety and essential performance of pulse oximeter equipment and in accordance with the FDA Guidelines for Pulse Oximeters – Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (2013).	The Arms error of the modified SpO_2 algorithm is lower or equivalent to the FDA-cleared SpO2 algorithm. The percent agreement between the modified SpO_2 QI outputs and the FDA-cleared SpO_2 QI outputs must be equal to or higher than 90%

III. NOTIFICATIONS OF PCCP IMPLEMENTATION TO USERS

Modifications described above will be incorporated into one of Empatica's quarterly releases of the Empatica Health Monitoring Platform (EHMP). In accordance with contractual obligations, enterprise customers will be notified of these updates through Customer Change Notification (CCN) documents at least 60 days in advance. Following completion of the internal Change Control process, the updated mobile application will be published on the App Store (iOS) and Google Play (Android), and users will receive an in-app notification when the new version becomes available.

As the EHMP is distributed solely to enterprise customers, updates are communicated in advance through CCNs, enabling users to review revised labeling materials prior to implementation. Any options for update deferral or opt-out are managed in accordance with customer agreements.

Each CCN will detail the nature and purpose of the modification, along with any impact on device performance. Associated performance characteristics will be reflected in the updated Instructions for Use (IFU), made available to professional users via the Care Portal. Version information for both the mobile application and Care Portal will be clearly displayed within their respective user interfaces, ensuring traceability of outputs to the corresponding software and algorithm version.

Known limitations, potential sources of bias, or performance issues affecting specific subpopulations will be transparently disclosed in both the CCNs and the IFU. When updates address such issues, changes in performance will be clearly described, and comparative pre- and post-update performance data will be included where relevant to support clinical understanding.

Validation methodologies and the characteristics of the evaluated populations—including demographic and clinical attributes—will be documented in the IFU, along with any stratified performance metrics that support clinical interpretation.
As the EHMP mobile application does not display SpO_2 values to patients, direct communication of updates to them is not required. These values are accessible only to professional users through the Care Portal. Accordingly, reanalysis of historical patient data and communication of result differences to patients are not applicable. However, if updates to the AI model result in clinically meaningful changes to outputs within the Care Portal, these changes will be clearly documented in the IFU and related professional user materials.

IV. CONCLUSION

The subject device has the same intended use, indications for use, and principles of operation as its predicate device. The technological characteristics are identical with the exception of the implementation of a PCCP, and this difference does not raise new questions of safety and effectiveness, it is our determination that the Empatica Health Monitoring Platform has a safety and effectiveness profile that is substantially equivalent to the predicate devices.