October 30, 2023

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

Re: K230457
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, BZQ, DQA, DRG, FLL, GZO, LEL
Dated: April 3, 2023
Received: September 29, 2023

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.

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.

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 Shih 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: 06/30/2023
*See PRA Statement below.*

Submission Number *(if known)*

K230457

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 27, 2023 |

### 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** | Current Health Monitoring System Gen 2 | Spry Health, Inc. | MSX<br>DQA<br>DRG<br>BZQ<br>BZG<br>FLL | K210133 |
| **Secondary** | Empatica Health Monitoring Platform | Empatica S.r.l. | DQA<br>DRG<br>LEL<br>FLL<br>GZO | K221282 |

| Predicate Device | Name | Submitter | Product Code(s) | 510(k) Number |
|---|---|---|---|---|
| **Secondary** | Loop System | Spry Health, Inc. | DQA<br>BZQ | K181352 |

None of these predicates have been subject to a design-related recall.

## IV. REFERENCE DEVICE

| Name | Submitter | Product Code(s) | 510(k) Number |
|---|---|---|---|
| Everion+ System | Biofourmis Singapore Pte. Ltd | MWI, MSX, BZQ | K213863 |

## 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) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| Common Name | Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) | System, Network and Communication, Physiological Monitors | Oximeter | Oximeter | N/A |
| Device Manufacturer | Empatica S.r.l. | Current Health Ltd. | Empatica S.r.l. | Spry Health Ltd. | N/A |
| Device Classification | II | II | II | II | N/A |
| 510(k) number | N/A | K210133 | K221282 | K181352 | N/A |
| Primary Product Code | MWI | MSX | DQA | DQA | N/A |
| Secondary Product Code | DQA, BZQ, DRG, GZO, LEL, FLL | FLL, DQA, BZQ, DRG, BZG | DRG, GZO, LEL, FLL | BZQ | 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 | The Current Wearable Health Monitoring System is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained | 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 to remotely monitor physiologic parameters in ambulatory individuals 18 years of age and older in | The Loop System is intended for adult patients in the home environment for passive, noninvasive, intermittent data collection of physiological parameters that will later be transmitted to a web server for remote review by a clinician. | The subject device indication for use includes the monitoring of a subset of the physiological parameters monitored by the primary predicate and additional parameters compared with the secondary predicates. |

| Features | Empatica Health Monitoring Platform (Subject Device) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| | 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.<br><br>The device is intended for continuous data collection supporting intermittent retrospective review of the following physiological parameters: :<br>• Pulse Rate,<br>• Blood Oxygen Saturation under no-motion conditions,<br>• Respiratory Rate under no motion conditions, | healthcare professionals. The Current Wearable Health Monitoring System is intended to provide visual and audible physiologic multi-parameter alarms. The Current Wearable Health Monitoring System is intended for temperature monitoring where monitoring temperature at the upper arm is clinically indicated. The Current Wearable Health Monitoring System is intended for continuous monitoring of the following parameters in adults:<br>• Pulse rate<br>• Oxygen saturation<br>• Temperature<br>• Movement<br><br>The Current Wearable Health Monitoring System is intended for intermittent or spot-check monitoring, in adults, of:<br>• Respiration rate | home-healthcare environments. The device supports the continuous monitoring of the following:<br>● Peripheral skin temperature,<br>● Electrodermal activity<br>● Blood Oxygen Saturation under no motion conditions<br>● Activity associated with movement during sleep<br>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, | The Loop System measures and records: • arterial oxygen saturation (SpO2) • heart rate (HR) • respiration rate (RR) All of these measurements are made when no motion is detected by the System. The Loop System device does not provide physiological alarms. | |

| Features | Empatica Health Monitoring Platform (Subject Device) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| | • Peripheral Skin Temperature,<br>• Electrodermal Activity,<br>• Activity associated with movement during sleep<br><br>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.<br><br>The Empatica Health Monitoring Platform is not intended for SpO2 monitoring in conditions of motion or low perfusion.<br><br>The Empatica Health Monitoring Platform is intended for peripheral skin temperature monitoring, where monitoring temperature | • Non-invasive blood pressure<br>• Lung function & spirometry<br>• Weight<br><br>The Current Wearable Health Monitoring System is not intended for use in high-acuity environments, such as ICU or operating rooms.<br><br>The Current Wearable Health Monitoring System is not intended for use on acutely ill cardiac patients with the potential to develop life threatening arrhythmias e.g. very fast atrial fibrillation. For these patients, they should be monitored using a device with continuous ECG. The Current Wearable Health Monitoring System is not a substitute for an ECG monitor.<br><br>The Current Wearable Health Monitoring System is | where monitoring temperature at the wrist is clinically indicated. | | |

| Features | Empatica Health Monitoring Platform (Subject Device) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| | at the wrist is clinically indicated.<br><br>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.<br><br>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 intended for SpO2 monitoring in conditions of high motion or low perfusion | | | |

| Features | Empatica Health Monitoring Platform (Subject Device) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| | not a substitute for an ECG monitor, and should not be used as the sole basis for clinical decision-making. | | | | |
| Target Population | Adult | Adult | Adult | Adult | The subject device and the predicates are identical |
| Anatomical Site | Wrist | Upper Arm | Wrist | Wrist | Clinical testing demonstrated the equivalence between the subject device and the predicates. The difference in wearing location on the body does not raise new questions of safety or efficacy. |
| Over the Counter or Rx | Rx | Rx | Rx | Rx | The subject device and the predicates are identical |
| Environment | Home | Professional Healthcare Facilities & Home | Home | Home | The subject device includes a subgroup of the predicates, hence this does not raise new questions of safety or efficacy. |

| Features | Empatica Health Monitoring Platform (Subject Device) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| Alarms | No | Yes | No | No | This difference does not raise new questions of safety or efficacy since the Empatica Health Monitoring Platform is not intended, by design, to include alarms for use in situations where the presence of alarms is a requirement for appropriate patient care. |
| User Interface | Device screen, Mobile device application, and cloud software platform | Mobile devices and a central station | Device screen, Mobile device application, and cloud software platform | Central station | The differences between the subject device and the predicates do not raise new questions of safety or efficacy |
| Energy Source | Battery | Battery | Battery | Battery | The subject device and the predicates are identical |
| Battery Type | Rechargeable Lithium-Ion | Rechargeable Lithium-Ion | Rechargeable Lithium-Ion | Rechargeable Lithium-Ion | The subject device and the predicates are identical |
| Wireless Communication Interface | Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud | IEEE 802.11 WiFi | Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud | Wireless (cellular connection) via charging station to Spry Server. | All the devices are designed to transmit their data to alternate devices or sites. The different technologies used do not raise new |

| Features | Empatica Health Monitoring Platform (Subject Device) | Current Health Monitoring System Gen 2 (K210133) | Empatica Health Monitoring Platform (K221282) | Loop System (K181352) | Analysis of differences |
|---|---|---|---|---|---|
| | | | | | questions of safety or efficacy |
| Patient contacting materials | Compliant to ISO 10993-1 | Compliant to ISO 10993-1 | Compliant to ISO 10993-1 | Compliant to ISO 10993-1 | The subject device and the predicates are identical |

| Technical and Performance Information for Pulse Rate | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **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. | N/A | HR measured by analyzing cyclic variations in 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 predicates are identical in that they all use the photoplethysmogram technology |
| PR Range | 24 – 240 beats per minute (bpm) | 30 – 240 beats per minute (bpm) | N/A | 25 – 250 beats per minute (bpm) | Clinically equivalent. The subject device and the predicates comply with ISO 80601-2-61 |
| PR Resolution | 1 bpm | 1 bpm | N/A | 1 bpm | The subject device and the predicates are identical |

| Technical and Performance Information for Pulse Rate | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Analysis of differences** |
| PR Accuracy | (no-motion) 3 bpm $A_{rms}$<br>(motion) 5 bpm $A_{rms}$ | (generic) ±3bpm | N/A | (no-motion) 3 bpm $A_{rms}$ | The subject device and the predicates all meet accuracy acceptance criteria thresholds recommended by FDA. The difference in accuracy does not impact the clinical safety of the product. |

| Technical and Performance Information for Respiratory Rate | | | | | | |
|---|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Everion+ System (K213863)** | **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 | Not used for substantial equivalence | N/A | Respiration rate (RR) is intermittently collected by analyzing cyclic variations in the photoplethysmogram . The diodes are mounted in the device such that they are in contact with the skin. | An optical sensor allows reflective photoplethysmography (PPG) measurements to be performed on the skin and underlying tissue | The core technology of photoplethysmography is identical between the subject device and the predicate. Technical differences are limited to differences in data collection frequency, which does not raise new questions of safety or effectiveness when |

| Technical and Performance Information for Respiratory Rate | | | | | | |
|---|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Everion+ System (K213863)** | **Analysis of differences** |
| | | | | | | considering performance of the device. Adequacy of performance using a continuous data sampling technology is supported by the reference device legally marketed for the same indication for use under the product code MWI, BZQ. |
| RR Range | 6 – 40 breaths per minute (brpm) | | N/A | 4 - 40 respirations per minute (RPM) | 6 – 30 breaths per minute (brpm) | The subject device has a different lower limit. The difference does not impact the clinical safety of the product. |
| RR Resolution | 1 brpm | | N/A | 1 RPM | | The subject device and the predicates are identical |
| RR Accuracy | 3 brpm $A_{rms}$ | | N/A | 3 RPM $A_{rms}$ | 3 brpm Arms | The subject device and the predicates are identical |

| Technical and Performance Information for Blood Oxygen Saturation | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **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 is measured by analyzing 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. | SpO2 relies on the principle that hemoglobin at different oxygenation states absorbs light differently based upon the wavelength of light. | SpO2 measured by analyzing 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 predicates are identical in that they all use the photoplethysmogram technology |
| $SpO_2$ Range | 70-100% | 70-100% | 70-100% | 70-100% | The subject device and the predicates are identical |
| $SpO_2$ Resolution | 1% | 1% | 1% | 1% | The subject device and the predicates are identical |
| $SpO_2$ Accuracy | 3% $A_{rms}$ | ± 2 Digits | 3% $A_{rms}$ | 3% $A_{rms}$ | The subject device and the predicates comply with ISO 80601-2-61 as well as with FDA Guidance for Pulse Oximeters (2013) |

No changes to the computation of Blood Oxygen Saturation ($SpO_2$) have been introduced in the version of the Empatica Health Monitoring Platform presented in this 510(k) submission compared with the recently cleared K221282. No additional clinical data or documentation has been attached to this 510(k) submission.

| Technical and Performance Information for Temperature | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Analysis of differences** |
| Technology | high-precision temperature sensor | In-Built Thermistor | high-precision temperature sensor | N/A | The subject device and the predicates are identical |
| Temperature Range | 0°C to 50°C | 0°C to 50°C | 0°C to 50°C | N/A | The subject device and the predicates are identical |
| Temperature Resolution | 0.1°C | 0.1°C | 0.1°C | N/A | The subject device and the predicates are identical |
| Temperature Accuracy | ± 0.1ºC within 30.0ºC - 45.0ºC range | ±0.1°C | ± 0.1ºC within 30.0ºC - 45.0ºC range | N/A | The subject device and the predicates are identical |

No changes to the computation of Peripheral Skin Temperature (TEMP) have been introduced in the version of the Empatica Health Monitoring Platform presented in this 510(k) submission compared with the recently cleared K221282. No additional bench test and validation data or documentation have been attached to this 510(k) submission.

| Technical and Performance Information for Electrodermal Activity | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Analysis of differences** |
| Technology | EDA is measured by analyzing detected changes in the conductivity of the superficial layers of the skin. | N/A | EDA is measured by analyzing detected changes in the conductivity of the superficial layers of the skin. | N/A | The subject device and the predicates are identical |
| EDA Range | 0.01 µS – 100 µS | N/A | 0.01 µS – 100 µS | N/A | The subject device and the predicates are identical |

| Technical and Performance Information for Electrodermal Activity | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Analysis of differences** |
| EDA Resolution | 1 digit ~ 55 pS | N/A | 1 digit ~ 55 pS | N/A | The subject device and the predicates are identical |

No changes to the computation of EDA (EDA) have been introduced in the version of the Empatica Health Monitoring Platform presented in this 510(k) submission compared with the recently cleared K221282. No additional bench test and validation data or documentation have been attached to this 510(k) submission.

| Technical and Performance Information for Activity and Sleep | | | | | |
|---|---|---|---|---|---|
| **Features** | **Empatica Health Monitoring Platform (Subject Device)** | **Current Health Monitoring System Gen 2 (K210133)** | **Empatica Health Monitoring Platform (K221282)** | **Loop System (K181352)** | **Analysis of differences** |
| Technology | Accelerometer | N/A | Accelerometer | N/A | The subject device and the predicate are identical |
| Accelerometer Type | Microelectromechanical system (MEMS)-based integrated circuit | N/A | Microelectromechanical system (MEMS)-based integrated circuit | N/A | The subject device and the predicate are identical |
| Accelerometer Sampling Rate | Digital method, 26 Hz – 208 Hz | N/A | Digital method, 26 Hz – 208 Hz | N/A | The subject device and the predicate are identical |
| Accelerometer Dynamic Range | ± 16 g | N/A | ± 16 g | N/A | The subject device and the predicate are identical |
| Accelerometer Sensitivity | 0.488 milli-g per Least Significant Bit | N/A | 0.488 milli-g per Least Significant Bit | N/A | The subject device and the predicate are identical |

No changes to the computation of ActivityCounts and activity during sleep (ACT and SLEEP) have been introduced in the version of the Empatica Health Monitoring Platform presented in this 510(k) submission compared with the recently cleared K221282. No additional bench test and validation data or documentation have been attached to this 510(k) submission

## II. PERFORMANCE DATA

**Non-Clinical testing (Bench testing)**

The following non-clinical (bench) testing was conducted to support a determination of substantial equivalence to the predicates and to demonstrate performance. The non-clinical bench tests included:

| Test Name | Test Description | Results |
|---|---|---|
| Biocompatibility testing | The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" September 4, 2020, and International Standard ISO 10993-1:2018 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:<br>● Cytotoxicity<br>● Sensitization<br>● Irritation<br>The EmbracePlus wearable device is considered surface contacting for a prolonged duration (>24 hours < 30 days) | Passed |
| Electrical safety testing | The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard IEC 60601-1 for electrical safety | Passed |
| Electromagnetic compatibility (EMC) testing | The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard IEC 60601-1-2 for EMC | Passed |
| Wireless Radio Communication | Empatica Health Monitoring Platform was tested to ensure it can communicate via wireless radio in its intended environment in compliance with FDA Radio Frequency Wireless Technology in Medical Devices Guidance, issued August 2013 | Passed |
| Usability testing | The Empatica Health Monitoring Platform was assessed with regards to usability for compliance with IEC 62366-1. The EmbracePlus was also tested in accordance with International Standard IEC 60601-1-6 for Usability of medical devices. | Passed |
| Home-Use testing | The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard IEC 60601-1-11 for medical devices used in home healthcare environments. | Passed |
| Cleaning validation | The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with International Standard ISO 17664 and AAMI TIR 30 to assess device cleaning procedure | Passed |
| Manual disinfection | The wearable device component of the Empatica Health Monitoring Platform, called EmbracePlus, was tested in accordance with ASTM E1837:2014 and AAMI TIR 12 to assess device low-level disinfection procedure | Passed |

| Test Name | Test Description | Results |
|---|---|---|
| Temperature measurement accuracy | The Empatica Health Monitoring Platform was tested to confirm the Skin temperature measurement accuracy and transient time complies with ISO 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)] to assess its accuracy. | Passed |
| Electrodermal activity measurement | The Empatica Health Monitoring Platform computed electrodermal activity (EDA) was tested to determine its equivalence to the predicate device Empatica E4. | Passed |
| Activity Counts/Sleep | Bench testing has been performed to demonstrate the equivalence of the Empatica Health Monitoring Platform activity counts and sleep detection with the predicate device. | Passed |

**Software Verification and Validation Testing**

Software verification and validation testing were conducted. Documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." All the Empatica Health Monitoring Platform software components were considered a "moderate" level of concern since a failure or latent flaw in the software could result in minor injury to the patient or operator.

**Cybersecurity**

Cybersecurity activities were conducted. Documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff, " Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." All the Empatica Health Monitoring Platform software components underwent appropriate cybersecurity assessment and testing.

**Animal study**

No animal studies were conducted as part of the submission to prove substantial equivalence.

**Clinical data - Pulse Rate**

The accuracy of the pulse rate values computed by the Empatica Health Monitoring Platform in motion and no-motion conditions, was investigated through the execution of three clinical studies on a total of 146 adult subjects. The Empatica Health Monitoring Platform was compared to a reference electrocardiogram.

The first study investigated the accuracy of the computed pulse rate values during no-motion conditions in 12 healthy adult subjects (Male=7, Female=5; Fitzpatrick I-IV=11, V-VI=1). This testing demonstrated an accuracy of ≤3 bpm $A_{rms}$ in no-motion conditions across a range of 24-240 beats per minute.

A second study investigated the accuracy of the computed pulse rate values in motion and no-motion conditions in 85 healthy adult subjects (Male=40, Female=45; Fitzpatrick I-IV=63, V-VI=22). This testing demonstrated an accuracy of ≤3 bpm $A_{rms}$ in no-motion conditions, and ≤5 bpm $A_{rms}$ in motion conditions across the range of 24-240 beats per minute.

The third study investigated the accuracy of the computed pulse rate values in motion and no-motion conditions in 49 adult subjects across a range of clinical conditions (Male=22, Female=27; Fitzpatrick I-IV=38, V-VI=11; Healthy=10, Subjects with PVCs=19, Subjects with other

comorbidities=20). This testing demonstrated an accuracy of ≤3 bpm $A_{rms}$ in no-motion conditions, and ≤5 bpm $A_{rms}$ in motion conditions across the range of 24-240 beats per minute.

Subgroup analyses on data pooled across the three studies were performed for sex, skin tone, and clinical condition, and confirmed adequate performance for the intended use in the target population.

**Clinical data - Respiratory Rate**

The accuracy of the respiratory rate values computed by the Empatica Health Monitoring Platform in no-motion conditions was investigated through the execution of four clinical studies on a total of 117 adult subjects. The Empatica Health Monitoring Platform was compared to a capnography reference device.

The first study investigated the accuracy of the computed respiratory rate values during no-motion conditions in 14 healthy adult subjects (Male=7, Female=7; Fitzpatrick I-IV=11, V-VI=3). This testing demonstrated an accuracy of ≤3 brpm $A_{rms}$ across a range of 6-40 breaths per minute.

The second study investigated the accuracy of the computed respiratory rate values during no-motion conditions in 46 healthy adult subjects (Male=23, Female=23; Fitzpatrick I-IV=33, V-VI=13). This testing demonstrated an accuracy of ≤3 brpm $A_{rms}$ across a range of 6-40 breaths per minute.

The third and fourth studies, considered confirmatory studies, investigated the accuracy of the computed respiratory rate values during no-motion conditions in subjects with various health conditions that might impact the accuracy of the computed values. In particular, the third study investigated a total of 17 adult subjects (Male=6, Female=11; Fitzpatrick I-IV=15, V-VI=2), and the fourth study investigated a total of 40 subjects (Male=18, Female=22; Fitzpatrick I-IV=31, V-VI=9). This testing confirmed an accuracy of ≤3 brpm Arms across a range of 6-40 breaths per minute.

Subgroup analyses on data pooled across the four studies were performed for sex and skin tone and confirmed adequate performance for the intended use in the target population.

No adverse events related to the device were encountered during the execution of both studies. The results of the clinical investigations demonstrate an effectiveness profile similar to the predicate devices.

## III. CONCLUSION

Based on the information presented in this 510(k) premarket notification, device performance and safety profile evaluated in clinical testing, and comparison with legally marketed predicate devices, it is our determination that the Empatica Health Monitoring Platform has a safety and effectiveness profile that is substantially equivalent to the predicate devices.