August 14, 2026

Empatica S.R.L.
Alberto Poli
Director, Quality & Regulatory Compliance
Via Enrico Stendhal, 36
Milan, 20144
Italy

Re: K260374
Trade/Device Name: Empatica Health Monitoring Platform for Parkinson's Disease Monitoring; EmbracePlus; EmbraceMini; Empatica Care; PKG Monitor by Empatica; Care Portal
Regulation Number: 21 CFR 882.1950
Regulation Name: Tremor Transducer
Regulatory Class: Class II
Product Code: GYD, ISD, NXQ, LEL
Dated: July 16, 2026
Received: July 16, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Patrick Antkowiak -
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Patrick Antkowiak
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine 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.

510(k) Number *(if known)*
K260374

Device Name
Empatica Health Monitoring Platform for Parkinson's Disease Monitoring;
EmbracePlus;
EmbraceMini;

Indications for Use *(Describe)*
The Empatica Health Monitoring Platform for Parkinson's Disease Monitoring is a wearable device and paired mobile and cloud-based software platform intended to quantify kinematics of movement tremor, bradykinesia, and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age.
The product also supports continuous data collection for monitoring the following physiological parameters:
- Physical movement associated with applications in physiological monitoring
- Activity associated with movement during sleep

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

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 Health Monitoring Platform for Parkinson's Disease Monitoring – 510(k)

510(k) Summary

Empatica Srl
Traditional 510(k)

Empatica Health Monitoring Platform for Parkinson's Disease Monitoring

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	August 13, 2026

II. DEVICE

Trade/Proprietary Name: Empatica Health Monitoring Platform for Parkinson's Disease Monitoring

Common/Usual Name: Remote Patient Monitoring System

Primary Product Code:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
882.1950	Transducer, Tremor	Class II	GYD	Neurology

Subsequent Product Code:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
890.5360	Exerciser, Measuring	Class II	ISD	Physical Medicine
890.5050	Reminder, Medication	Class I	NXQ	Physical Medicine
882.5050	Device, Sleep Assessment	Class II	LEL	Neurology

III. PREDICATE DEVICES

Predicate Device	Name	Submitter	Product Code(s)	510(k) Number
Primary	Personal Kinetigraph (PKG) System Gen 2 Plus	Gkc Manufacturing Pty, Ltd.	GYD ISD NXQ	K211887
Secondary	EmbraceMini	Empatica S.r.l.	LEL	K252981
Secondary	Empatica Health Monitoring Platform	Empatica S.r.l.	MWI, BZQ, DQA, DRG, FLL, GZO, LEL	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 for Parkinson's Disease Monitoring is a wearable device and software platform composed by:

- A wearable medical device called EmbracePlus or EmbraceMini,
- A mobile application running on smartphones called "Empatica Care",
- A mobile application running on smartphones called "PKG Monitor by Empatica"
- A cloud-based software platform named "Care Portal".

The wearable device (EmbracePlus or EmbraceMini) 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 Empatica Care or PKG Monitor by Empatica is up and running. The data received are analyzed by one of the app software modules, EmpaDSP, which compute the user physiological parameters. The mobile applications are also responsible for transmitting, over cellular or Wi-Fi connection sensors' raw data, device information, 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.

VI. INDICATION FOR USE

The Empatica Health Monitoring Platform for Parkinson's Disease Monitoring is a wearable device and paired mobile and cloud-based software platform intended to quantify kinematics of movement tremor, bradykinesia, and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is indicated for use in individuals 46 to 83 years of age.

The product also supports continuous data collection for monitoring the following physiological parameters:

- Physical movement associated with applications in physiological monitoring
- Activity associated with movement during sleep

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

I. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

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

Features	Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)	Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)	EmbraceMini (K252981)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
Common Name	Transducer, Tremor	Transducer, Tremor	device, sleep assessment	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)	N/A
Device Manufacturer	Empatica S.r.l.	GKC Manufacturing Pty Ltd	Empatica S.r.l.	Empatica S.r.l.	N/A
Device Classification	II	II	II	II	N/A
510(k) number	N/A	K211887	K252981	K230457	N/A
Primary Product Code	GYD	GYD	LEL	MWI	N/A
Associated Product Code	ISD, NXQ, LEL	ISD, NXQ	-	BZQ, DQA, DRG, FLL, GZO, LEL	N/A
Intended Use/Indications for Use	The Empatica Health Monitoring Platform for Parkinson's Disease Monitoring is a wearable device and paired mobile and cloud-based software platform intended to quantify kinematics of movement tremor, bradykinesia, and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The device is	The Personal Kinetigraph (PKG) is intended to quantify kinematics of movement disorder symptoms in conditions such as Parkinson's disease, including tremor, bradykinesia and dyskinesia. It includes a medication reminder, an event marker and is intended to monitor activity associated with movement during sleep. The	EmbraceMini is a wearable device intended to be used by trained healthcare professionals or researchers to remotely monitor limb or body movements in ambulatory individuals in home-healthcare environments and	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	The subject device's intended use adds quantification of movement tremor, bradykinesia, and dyskinesia, enabled by previously cleared PKG algorithms compared against the primary predicate

Features	Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)	Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)	EmbraceMini (K252981)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
	indicated for use in individuals 46 to 83 years of age. The product also supports continuous data collection for monitoring the following physiological parameters: ● Physical movement associated with applications in physiological monitoring ● Activity associated with movement during sleep The Empatica Health Monitoring Platform can also be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	device is indicated for use in individuals 46 to 83 years of age.	professional healthcare environments. The device supports continuous data collection for monitoring the following physiological parameters: ● Physical movement associated with applications in physiological monitoring ● Activity associated with movement during sleep EmbraceMini can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	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.	(K211887) rather than by any change to the EmbracePlus hardware, which is unchanged from K230457. The subject device also omits several physiological parameters claimed by K230457 (pulse rate, SpO2, respiratory rate, skin temperature), representing a narrowing rather than an expansion of intended use. These differences do not raise new questions of safety or effectiveness, as the hardware is identical and the new algorithm outputs are supported by performance testing.

Features	Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)	Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)	EmbraceMini (K252981)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
				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	

Features	Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)	Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)	EmbraceMini (K252981)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
				should not be used as the sole basis for clinical decision-making.	
Target Population	Patients aged 46-83 with Parkinson's disease and/or other movement disorders.	Patients aged 46-83 with Parkinson's disease and/or other movement disorders.	Adult (age 18 and up)	Adult (age 18 and up)	The subject device and the primary predicate are identical. The subject device has a narrower intended patient population compared to the secondary predicates. This difference does not raise new concerns regarding safety and effectiveness.
Anatomical Site	Wrist	Wrist	Wrist	Wrist	The subject device and the predicate are identical
Over the Counter or Rx	Rx	Rx	Rx	Rx	The subject device and the predicate are identical
Environment	Home	Home	Home	Home	The subject device and the predicates are identical.

Features	Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)	Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)	EmbraceMini (K252981)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
Alarms	No	No	No	No	The subject device and the predicates are identical.
User Interface	● **EmbracePlus wearable device:** Device screen, Mobile device application, and cloud software platform ● **EmbraceMini wearable device**: Device LED, Mobile device application, and cloud software platform	Device screen, and cloud software platform	Device LED	Device screen, Mobile device application, and cloud software platform	The differences between the subject device and the predicates do not introduce any issues 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 differences between the subject device and the predicates do not raise new questions of safety or efficacy
Wireless Communication Interface	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	N/A collected data are transferred to the Clinic Server using docking station	Bluetooth® Low Energy (device to mobile device)	Bluetooth® Low Energy (device to mobile device)	The subject device and the primary predicate differ in the data transfer process from the device to healthcare professional portal. This difference

Features	Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)	Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)	EmbraceMini (K252981)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
					does not raise different questions of safety and effectiveness as the data transfer process of the subject device has been subject to verification activities.
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 predicate are identical

Technical and Performance Information for Parkinson's Disease Monitoring measures					
Features	**Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)**	**Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)**	**EmbraceMini (K252981)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
Technology used for bradykinesia, dyskinesia and tremor computation	Accelerometer and proprietary algorithms.	Accelerometer and proprietary algorithms.	-	-	The subject device and the primary predicate are identical. The algorithms used by the predicate device have been acquired

Technical and Performance Information for Parkinson's Disease Monitoring measures					
Features	**Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)**	**Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)**	**EmbraceMini (K252981)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
					by Empatica through the acquisition of the manufacturer.
Accelerometer Type	Microelectromechanical system (MEMS)-based integrated circuit	Microelectromechanical system (MEMS)-based integrated circuit	Microelectromechanical system (MEMS)-based integrated circuit	Microelectromechanical system (MEMS)-based integrated circuit	The subject device and the predicates are identical
Accelerometer Sampling Rate	Digital method, 26 Hz – 208 Hz	32Hz (configurable)	Digital method, 26 Hz – 208 Hz	Digital method, 26 Hz – 208 Hz	The subject device and the primary predicate have different sampling rate, however the subject device configurable sampling rate contains the primary predicate declared sampling rate. This difference does not raise safety and efficacy issues since bench testing have been performed to ensure equivalence between the two

Technical and Performance Information for Parkinson's Disease Monitoring measures					
Features	**Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)**	**Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)**	**EmbraceMini (K252981)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
					devices. The subject device and the secondary predicate are identical
Accelerometer Dynamic Range	± 16 g	± 4 g	± 16 g	± 16 g	The subject device and the primary predicate have different dynamic range, however the subject device dynamic range contains the primary predicate declared range. This difference does not raise safety and efficacy issues since bench testing have been performed to ensure equivalence between the two devices. The subject device and the secondary predicate are identical

Technical and Performance Information for Parkinson's Disease Monitoring measures					
Features	**Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)**	**Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)**	**EmbraceMini (K252981)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
Accelerometer Sensitivity	0.488 milli-g per Least Significant Bit	1.95mg	0.488 milli-g per Least Significant Bit	0.488 milli-g per Least Significant Bit	The subject device and the primary predicate have different accelerometer sensitivity. The subject device has a higher sensitivity than the predicate. This difference does not raise safety and efficacy issues since bench testing have been performed to ensure equivalence between the two devices. The subject device and the secondary predicate are identical.

Technical and Performance Information for Activity and Sleep					
Features	**Empatica Health Monitoring Platform for Parkinson's Disease Monitoring (Subject Device)**	**Personal Kinetigraph (PKG) System Gen 2 Plus (K211887)**	**EmbraceMini (K252981)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
Technology	Accelerometer	-	Accelerometer	Accelerometer	The subject device and the predicate are identical
Accelerometer Type	Microelectromechanical system (MEMS)-based integrated circuit	-	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	Digital method, 26 Hz – 208 Hz	The subject device and the predicate are identical
Accelerometer Dynamic Range	± 16 g	-	± 16 g	± 16 g	The primary predicate does not claim monitoring of sleep. The subject device and the secondary predicates are identical.
Accelerometer Sensitivity	0.488 milli-g per Least Significant Bit	-	0.488 milli-g per Least Significant Bit	0.488 milli-g per Least Significant Bit	The primary predicate does not claim monitoring of sleep. The subject device and the secondary predicates 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 K230457 and K252981. No additional bench test and validation data or documentation have been attached to this 510(k) submission

VII. 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 devices were 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 8, 2023, 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 testing included the following tests: ● Cytotoxicity ● Sensitization ● Irritation The wearable devices are considered skin surface contacting for a permanent duration (> 30 days).	Passed
Electrical safety testing	The wearable devices were tested in accordance with International Standard IEC 60601-1 for electrical safety.	Passed
Electromagnetic compatibility (EMC) testing	The wearable devices were tested in accordance with International Standard IEC 60601-1-2 for EMC.	Passed
Wireless Radio Communication	The wearable devices were 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 wearable devices were assessed with regards to usability for compliance with IEC 62366-1. The wearable devices were also tested in accordance with International Standard IEC 60601-1-6 for Usability of medical devices.	Passed
Home-Use testing	The wearable devices were tested in accordance with International Standard IEC 60601-1-11 for medical devices used in home healthcare environments.	Passed
Bradykinesia, Dyskinesia and Tremor — Bench testing (simulated motion)	Bench testing was performed using a controlled robotic motion simulator to demonstrate equivalence of Bradykinesia Score (BKS), Dyskinesia Score (DKS), and Tremor Score (TS) algorithm outputs between the subject devices (EmbraceMini, EmbracePlus) and the predicate PKG Health Watch. Three device pairs per subject device were tested using programmed motion sequences spanning the clinical severity range for each measure.	Pooled agreement across device pairs: BKS 100% (point-wise <80 and classification), DKS 97.5–98.5%, Tremor 100%. All pre-specified acceptance criteria met.
Bradykinesia, Dyskinesia and Tremor — Enhanced bench testing (real-	Enhanced bench testing was performed using robotic replay of real-world motion recordings collected via the predicate device from 200 patients with idiopathic Parkinson's disease (ages 59–75). Motion trajectories were replayed on three device pairs per subject device to evaluate BKS, DKS, and TS algorithm output agreement under real-world-representative	Pooled agreement across device pairs: BKS 96.1–97.0% (point-wise <80), 100% (classification), DKS 95.3–96.1%, Tremor 99.2–99.3% (classification).

Test Name	Test Description	Results
world motion replay)	motion conditions, including stratified severity-based sampling and continuous-block temporal agreement analysis.	Supportive temporal correlation analysis showed mean Pearson correlation ≥0.94 (BKS, DKS) and ≥0.93 (TS) between subject and predicate devices, with all 95% CI lower bounds exceeding the pre-specified 0.9 threshold. All pre-specified acceptance criteria met.
Bradykinesia, Dyskinesia and Tremor — Human testing (real-world paired wear)	Simultaneous, co-located paired-wear testing of subject and predicate devices in 11 PD patients under naturalistic conditions, evaluating BKS, DKS, and TS algorithm output agreement.	Pooled agreement: BKS 96.5–97.2% (point-wise <80), 99.7–99.8% (classification), DKS 92.3–93.8%, Tremor 95.1–96.1% (classification). All pre-specified acceptance criteria met for both subject devices.
Activity Counts/Sleep	Since the hardware components of the subjects device were not subject to changes since their most recent clearance (K230457 for EmbracePlus and K252981 for EmbraceMini) and the algorithms used to compute activity counts and Sleep are unchanged no additional bench testing has been performed.	-

Software Verification and Validation Testing

Software verification and validation testing have been successfully conducted. Software documentation was provided as recommended by the FDA's Guidance for Industry and FDA Staff "Content of Premarket Submissions for Device Software Functions" for Basic documentation level.

Cybersecurity

Cybersecurity activities have been conducted and an assessment made on individual component risks. Documentation has been provided with this application as recommended by the FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". The product software components underwent appropriate cybersecurity assessment and testing.

Animal study

No animal studies have been conducted as part of this submission to prove substantial equivalence, as the device is not intended for contact with compromised skin.

Clinical Study

No clinical studies have been performed on the subject device as part of this submission to prove substantial equivalence. A device performance evaluation was conducted to assess algorithm output agreement between the subject and predicate devices under real-world use conditions.

VIII. CONCLUSION

Based on the information presented in this 510(k) premarket notifications, The Empatica Health Monitoring Platform for Parkinson's Disease Monitoring is substantially equivalent to the predicate devices. The product is as safe and effective as the currently marketed predicate device.

Based on testing and comparison with the predicate device, the product indicated no adverse indications or results. It is our determination that the product is safe, effective and performs within its design specifications, and is substantially equivalent to the predicate device.