December 22, 2025

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

Re: K252981
Trade/Device Name: EmbraceMini
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback device
Regulatory Class: Class II
Product Code: LEL
Dated: September 17, 2025
Received: September 17, 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.

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,

Patrick Antkowiak -S

for
Jay Gupta
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)*
K252981

Device Name
EmbraceMini

Indications for Use *(Describe)*
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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Empatica Srl
Traditional 510(k)
EmbraceMini

EmbraceMini – 510(k)

510(k) Summary

Version 2.0

Empatica Srl
Traditional 510(k)
EmbraceMini

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, 2025

II. DEVICE

Trade/Proprietary Name: EmbraceMini
Common/Usual Name: Remote Patient Monitoring System

Primary Product Code:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
882.5050	Device, Sleep Assessment	Class II	LEL	Neurology

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

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 Care App is running. The Care App is a component of the FDA cleared Empatica Health Monitoring Platform

The data received is analyzed by one of the Care App software modules, EmpaDSP, which computes the user's 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.

EmbraceMini is intended for retrospective remote monitoring of physiological parameters in ambulatory adults in home-healthcare environments.

VI. INDICATION FOR USE

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 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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

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

Features	EmbraceMini (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
Common Name	device, sleep assessment	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	The subject device and the predicate are identical
Product Code	LEL	MWI	The subject device has as product code one of the associated product codes of the predicate.
Associated Product Code(s)	N/A	DQA, BZQ, DRG, GZO, LEL, FLL	The subject device does not have any associated product code.
Intended Use/Indications for Use	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 professional healthcare environments. The device supports continuous data collection for monitoring the following physiological parameters:	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	The subject device as more limited indication for use, specifically it can only monitor physical movement and activity associated with movement during sleep. This different does not raise additional

Features	EmbraceMini (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
	● 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.	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.	safety or performance concerns.

Features	EmbraceMini (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
		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.	
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 predicates are identical.

Features	EmbraceMini (Subject Device)	Empatica Health Monitoring Platform (K230457)	Analysis of differences
Alarms	No	No	The subject device and the predicates are identical.
User Interface	Device LED.	Device screen, Mobile device application, and cloud software platform	The subject device has only an LED. The subject device and predicate device share the same mobile application and cloud software platform.
Energy Source	Battery	Battery	The subject device and the predicates are identical
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	The subject device and the predicates are identical
Wireless Communication Interface	Bluetooth® Low Energy (device to mobile device)	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

Technical and Performance Information for Activity and Sleep			
Features	**EmrbaceMini (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

Technical and Performance Information for Activity and Sleep			
Features	**EmrbaceMini (Subject Device)**	**Empatica Health Monitoring Platform (K230457)**	**Analysis of differences**
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 EmbraceMini 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 predicate device. Validation testing has been performed to ensure equivalence between EmbraceMini and the predicate.

VIII. 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	EmbraceMini 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 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 EmbraceMini is considered skin surface contacting for a permanent duration (> 30 days).	Passed
Electrical safety testing	EmbraceMini was tested in accordance with International Standard IEC 60601-1 for electrical safety.	Passed
Electromagnetic compatibility (EMC) testing	EmbraceMini was tested in accordance with International Standard IEC 60601-1-2 for EMC.	Passed
Wireless Radio Communication	EmbraceMini 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	EmbraceMini has been assessed with regards to usability for compliance with IEC 62366-1. EmbraceMini was also tested in accordance with International Standard IEC 60601-1-6 for Usability of medical devices.	Passed
Home-Use testing	EmbraceMini was tested in accordance with International Standard IEC 60601-1-11 for medical devices used in home healthcare environments.	Passed
Activity Counts/Sleep	Bench testing has been performed to demonstrate the equivalence of EmbraceMini activity counts and sleep detection with the predicate device.	Passed

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". EmbraceMini 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

IX. CONCLUSION

Based on the information presented in this 510(k) premarket notifications, EmbraceMini is substantially equivalent to the predicate devices. EmbraceMini is as safe and effective as the currently marketed predicate device.
Based on testing and comparison with the predicate device, EmbraceMini indicated no adverse indications or results. It is our determination that EmbraceMini is safe, effective and performs within its design specifications, and is substantially equivalent to the predicate device.