



June 19, 2025

Empatica, Srl
Alberto Poli
Director, Quality & Regulatory Compliance
Via Stendhal 36
Milano, Milano 20144
Italy

Re: K250515

Trade/Device Name: EpiMonitor

Regulation Number: 21 CFR 882.1580

Regulation Name: Non-Electroencephalogram (EEG) Physiological Signal Based Seizure Monitoring System

Regulatory Class: Class II

Product Code: POS, LEL, FLL

Dated: February 21, 2025

Received: February 21, 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

Indications for Use

510(k) Number (if known)
K250515

Device Name
EpiMonitor

Indications for Use (Describe)

EpiMonitor is a prescription only medical device system composed of a wearable device “EmbracePlus” and paired mobile software application “EpiMonitor” intended as an adjunct to seizure monitoring in adults and children aged 6 and up in a home environment or healthcare facilities. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with either primary or secondary generalized tonic clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, the wearable device component of EpiMonitor sends a command to a paired mobile device where the EpiMonitor App is programmed to initiate an alert to a designated caregiver. The EpiMonitor app incorporates additional detection sensitivity modes, "high" for use during periods of rest or sleeping or "low" for use during periods of low-intensity activity, in order to reduce false alarm incidents.

EpiMonitor records, stores and transmits accelerometers, EDA, Peripheral skin temperature and activity data for subsequent retrospective review by a trained healthcare professional via a cloud-based software.

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.

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Special 510(k)
EpiMonitor



EpiMonitor – 510(k)

510(k) Summary

Empatica Srl Special 510(k)

EpiMonitor

510(k) Summary

I. SUBMITTER

Company Name	Empatica Srl
Establishment Registration Number	3012933969
Contact Person	Alberto Poli, Regulatory Affairs & Quality Manager
Contact Person email	apo@empatica.com
Address	Via Stendhal, 36 - 20144, Milan, Italy
Telephone Number	+39 02 36165068
Date prepared	May 21, 2025

II. DEVICE

Trade/Proprietary Name: EpiMonitor

Common/Usual Name: non-EEG physiological signal based seizure monitoring system

Primary Product Code:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
882.1580	Non-electroencephalogram (EEG) physiological signal based seizure monitoring system	Class II	POS	Neurology

Secondary Product Codes:

Classification Regulation	Classification Name	Device Class	Product Code	Classification Panel
882.5050	Device, Sleep Assessment	Class II	LEL	Neurology
880.2910	Thermometer, Electronic, Clinical	Class II	FLL	General Hospital

III. PREDICATE DEVICES

Predicate Device	Name	Submitter	Product Code(s) Primary (Secondary)	510(k) Number
Primary	EpiMonitor	Empatica S.r.l.	POS, LEL, FLL	K232915

The predicate has been subject to a design-related recall.

No reference devices were used in this submission.

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EpiMonitor

IV. DEVICE DESCRIPTION

The EpiMonitor system consists of a wearable device and mobile application:

- A wearable medical device called EmbracePlus,
- A mobile application running on smartphones called "EpiMonitor"

The EmbracePlus is worn on the user's wrist and continuously collects raw data via specific sensors, these data are continuously analyzed by an on-board algorithm (EpiAlgo 2.1), which assesses the physiological data and determines if the user may be undergoing a generalized tonic-clonic seizure (GTCS). The EpiAlgo has been validated through testing, using the gold-standard video-Electroencephalogram (EEG) methodology designed by a group of epileptologists at a top level 4 epilepsy center, from epilepsy patients experiencing GTCSs in hospital Epilepsy Monitoring Units. When a likely GTCS is detected, EmbracePlus sends, via Bluetooth Low Energy, a message to the EpiMonitor app. The EpiMonitor app communicates to the Empatica Cloud which initiates, through the external provider a voice call and SMS text message is sent to summon the attention of user-designated caregiver(s).

In addition to initiating alerts, the EpiMonitor app also continuously receives all the raw sensor data collected by the EmbracePlus. These data are analyzed by one of the EpiMonitor app software modules, EmpaDSP (paragraph 2.3.2), which computes the additional physiological parameters, such as activity during sleep and peripheral skin temperature.

The EpiMonitor App is also responsible for transmitting, over a cellular data plan or Wi-Fi connection the sensors' raw data, device information, and computed physiological parameters to the Empatica Cloud. On the Empatica Cloud, these data are stored, and made available to healthcare providers via a specific cloud-based software called Care Monitoring Portal.

V. INDICATION FOR USE

EpiMonitor is a prescription only medical device system composed of a wearable device "EmbracePlus" and paired mobile software application "EpiMonitor" intended as an adjunct to seizure monitoring in adults and children aged 6 and up in a home environment or healthcare facilities. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with either primary or secondary generalized tonic clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, the wearable device component of EpiMonitor sends a command to a paired mobile device where the EpiMonitor App is programmed to initiate an alert to a designated caregiver. The EpiMonitor app incorporates additional detection sensitivity modes, "high" for use during periods of rest or sleeping or "low" for use during periods of low-intensity activity, in order to reduce false alarm incidents.

EpiMonitor records, stores and transmits accelerometer, EDA, peripheral skin temperature and activity data for subsequent retrospective review by a trained healthcare professional via a cloud-based software.

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EpiMonitor

I. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The EpiMonitor system, including the EmbracePlus wearable and EpiMonitor App, is substantially equivalent to the identified predicate devices.

The devices have similar Indications for Use, features, technology, and accuracy.

Features	EpiMonitor (Subject Device)	EpiMonitor (K232915) Predicate	Analysis of differences
Common Name	Non-EEG physiological signal based seizure monitoring system	Non-EEG physiological signal based seizure monitoring system	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	K232915	N/A
Primary Product Code	POS	POS	N/A
Secondary Product Code	LEL, FLL	LEL, FLL	N/A
Sterility	Non-Sterile	Non-Sterile	N/A
Intended Use	EpiMonitor is intended as an adjunct for the detection and alerting of possible seizures in patients with epilepsy or at risk of having epilepsy, and for remote monitoring of physiological parameters which may provide	EpiMonitor is intended as an adjunct for the detection and alerting of possible seizures in patients with epilepsy or at risk of having epilepsy, and for remote monitoring of physiological parameters which may provide	The subject device and the predicate device have the same intended use.

Empatica Srl Special 510(k) EpiMonitor

Features	EpiMonitor (Subject Device)	EpiMonitor (K232915) Predicate	Analysis of differences
	supplementary support in the clinical management of epilepsy.	supplementary support in the clinical management of epilepsy.	
Indications for Use	<p>EpiMonitor is a prescription only medical device system composed of a wearable device “EmbracePlus” and paired mobile software application “EpiMonitor” intended as an adjunct to seizure monitoring in adults and children aged 6 and up in a home environment or healthcare facilities. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with either primary or secondary generalized tonic clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, the wearable device component of EpiMonitor sends a command to a paired mobile device where the EpiMonitor App is programmed to initiate an alert to a designated caregiver. The EpiMonitor app incorporates additional detection sensitivity modes, "high" for use during periods of rest or sleeping or "low" for use during periods of low-intensity activity, in order to reduce false alarm incidents EpiMonitor records, stores and transmits accelerometers, EDA, Peripheral skin temperature and activity data for subsequent</p>	<p>EpiMonitor is a prescription only medical device system composed of a wearable device “EmbracePlus” and paired mobile software application “EpiMonitor” intended as an adjunct to seizure monitoring in adults and children aged 6 and up in a home environment or healthcare facilities. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with either primary or secondary generalized tonic clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, the wearable device component of EpiMonitor sends a command to a paired mobile device where the EpiMonitor App is programmed to initiate an alert to a designated caregiver. The EpiMonitor app incorporates additional detection sensitivity modes, "high" for use during periods of rest or sleeping or "low" for use during periods of low-intensity activity, in order to reduce false alarm incidents</p>	<p>The subject device and the predicate device have the same indications for use.</p>

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EpiMonitor

Features	EpiMonitor (Subject Device)	EpiMonitor (K232915) Predicate	Analysis of differences
	retrospective review by a trained healthcare professional via a cloud-based software.	EpiMonitor records, stores and transmits accelerometers, EDA, Peripheral skin temperature and activity data for subsequent retrospective review by a trained healthcare professional via a cloud-based software.	
Target Population	Adults and Children aged 6 years and above	Adults and Children aged 6 years and above	The subject device and the predicate have the same target population
Anatomical Site	Wrist	Wrist	The subject device and the predicates are identical
Over the Counter or Rx	Rx	Rx	The subject device and the predicates are identical
Environment	Professional Healthcare Facilities & Home environment	Professional Healthcare Facilities & Home environment	The subject device and the predicate are identical.
User Interface	Layperson: Device screen with two side buttons Mobile device application (EpiMonitor) Caregiver(s): Voice call and SMS	Layperson: Device screen with two side buttons Mobile device application (EpiMonitor) Caregiver(s): Voice call and SMS	The subject device and the predicate have same user interface.
Energy Source	Battery	Battery	The subject device and the predicate are identical

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EpiMonitor

Features	EpiMonitor (Subject Device)	EpiMonitor (K232915) Predicate	Analysis of differences
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	The subject device and the predicate are identical
Wireless Communication Interface	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	Bluetooth® Low Energy (device to mobile device) IEEE 802.11 WiFi/cellular to Empatica cloud	The subject device and the predicate are identical
Patient contacting materials	Compliant to ISO 10993-1 Device housing: <ul style="list-style-type: none"> ● Polycarbonate ● Stainless steel ● Gorilla Glass 3 ● Thermoplastic Polyurethane Band: <ul style="list-style-type: none"> ● Elastane and Polyamide 	Compliant to ISO 10993-1 Device housing: <ul style="list-style-type: none"> ● Polycarbonate ● Stainless steel ● Gorilla Glass 3 ● Thermoplastic Polyurethane Band: <ul style="list-style-type: none"> ● Silicone Rubber ● Stainless Steel 	The subject device and the secondary predicate are identical in their contacting materials. The subject device and primary predicate utilize similar materials. All materials are demonstrated to be compliant to ISO 10993-1.
EDA Sensors Location	Wrist - Dorsal	Wrist - Ventral	Verification testing demonstrated the equivalence between the subject device and the predicate. The difference in EDA sensors location does not raise new questions of safety or efficacy.
Principle of Operation (Seizure Detection Algorithm)	EpiAlgo (Version 2.1) - Uses algorithms to analyze EDA and accelerometer data to detect patterns in the data that may be associated with GTC seizures.	EpiAlgo (Version 2.1) - Uses algorithms to analyze EDA and accelerometer data to detect patterns in the data that may be associated with GTC seizures.	The subject device and the predicate are identical.

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II. PERFORMANCE DATA

Non-Clinical testing (Bench testing)

The following non-clinical (bench) testing was conducted to provide evidence of the implemented changes to EmbracePlus do not affect the product safety and effectiveness and to support a determination of substantial equivalence to the predicate. The non-clinical bench tests included:

Test Name	Test Description	Results
Wireless Radio Communication	The EpiMonitor System 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
Electrodermal Activity measurement	The wearable device component of the EpiMonitor System, EmbracePlus, computed electrodermal activity (EDA) has been tested to determine its equivalence to the predicate device Embrace.	Passed
Algorithm Performance (Bench Testing)	Bench testing comparing the equivalence in performance of Embrace and EpiMonitor devices was conducted using simulated seizure patterns based on motion and electrodermal activity data derived from confirmed convulsive seizures.	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, along with software documents to comply with the special controls applicable to products regulated under 21 CFR 882.1580. All the EpiMonitor System 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 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". All the EpiMonitor System 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. Clinical studies were performed on EpiAlgo ver 2.1 to support clearance of the predicate device (K181861).

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Clinical Data Analysis

Clinical performance of the EpiAlgo ver 2.1 on the EmbracePlus device was confirmed by bench testing to be equivalent to the performance of the Embrace device presented in K181861, when using the standard alerting threshold during rest activities (High-Sensitivity). To assess the performance of EpiAlgo ver 2.1 on the EmbracePlus device using the Low-Sensitivity threshold introduced in the EpiMonitor system, two retrospective analyses of previously collected clinical data were conducted. The Low-Sensitivity threshold is an optional alerting mode for use in low-intensity daytime activities, when a patient may prefer an alerting threshold that optimizes for reduction in false alarm rates.

Using adjudicated tonic-clonic seizure data collected from patients observed in Epilepsy Monitoring Units, Positive Percent Agreement (PPA) and false alarm rate per 24 hours (FAR) were calculated for adult and pediatric subgroups during non-rest activities (Tables 1 and 2).

Table 1 - Positive Percent Agreement applying Low-Sensitivity Mode to Epilepsy Monitoring Unit data

age	# patients	# GTCS	# detected GTCS	PPA	corrected PPA	Confidence Interval - PPA	
6-21	12	19	17	0.895	0.791	0.619	0.925
>21	12	17	17	1.000	0.905	0.891	0.917

Table 2 – False Alarm Rate applying Low-Sensitivity Mode to Epilepsy Monitoring Unit data

age	# patients	# FA	# days	Overall FAR	Confidence Interval - Overall FAR		Mean FAR	Confidence Interval – Mean FAR	
6-21	80	62	88.94	0.70	0.41	1.06	0.91	0.44	1.57
>21	61	43	152.68	0.28	0.15	0.46	0.33	0.17	0.53

A second longitudinal analysis of real-world data was then conducted to ensure that a wide range of non-rest activities in home settings were captured. Tables 3 and 4 describe the performance of the EpiAlgo ver 2.1 during non-rest activities in home settings for both adult and pediatric subgroups.

Table 3 - Positive Percent Agreement applying Low-Sensitivity Mode to real-world data captured by Embrace2

age	# patients	# GTCS	# detected GTCS	PPA	corrected PPA	Confidence Interval PPA	
6-21	601	1157	1011	0.87	0.86	0.78	0.92
>21	843	3625	2896	0.8	0.77	0.64	0.87

Table 4 – False Alarm Rate applying Low-Sensitivity Mode to real-world data captured by Embrace2

age	# patients	# FA	# days	Overall FAR	Confidence Interval - Overall FAR		Mean FAR	Confidence Interval - Mean FAR	
6-21	601	12808	37594.2	0.34	0.23	0.50	0.35	0.28	0.45

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>21	843	14308	56389.1	0.25	0.22	0.30	0.29	0.26	0.33
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Analysis of performance for the Low-Sensitivity alerting mode in the EpiMonitor system demonstrated acceptable seizure detection accuracy and a reduced rate of false alerts.

NOTE: The longitudinal analysis of real-world data was based on analysis of sensor data captured using the Embrace2 wearable device.

III. CONCLUSION

Based on the information presented in this 510(k) premarket notification, EpiMonitor is considered to be substantially equivalent to the predicate devices on the basis of safety and effectiveness.

This has been determined on the basis of the testing, as summarized in this document, and the physical and technological comparisons made to the predicate devices. The EpiMonitor System has demonstrated no adverse indications or results and performs within its design specifications.