February 15, 2024

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

Re: K232915
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: January 18, 2024
Received: January 18, 2024

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,

FDA 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)*
K232915

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 accelerometer, 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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Traditional 510(k)

EpiMonitor

EpiMonitor – 510(k)

510(k) Summary

Version 3.0

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Traditional 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	February 14, 2024

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	Embrace	Empatica S.r.l.	POS	K181861
Secondary	Empatica Health Monitoring Platform	Empatica S.r.l.	DQA (DRG, FLL, GZO, LEL)	K221282

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

No reference devices were used in this submission.

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Traditional 510(k)
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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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)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
Common Name	Non-EEG physiological signal based seizure monitoring system	Non-EEG physiological signal based seizure monitoring system	Oximeter	N/A
Device Manufacturer	Empatica S.r.l.	Empatica S.r.l	Empatica S.r.l.	N/A
Device Classification	II	II	II	N/A
510(k) number	N/A	K181861	K221282	N/A
Primary Product Code	POS	POS	DQA	N/A
Secondary Product Code	N/A	N/A	DRG, GZO, LEL, FLL	N/A
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	N/A
Intended Use	EpiMonitor is intended as an adjunct for the detection and alerting of possible seizures in	Non-EEG physiological signal based seizure monitoring system	The Empatica Health Monitoring Platform is intended for the remote monitoring of physiological	The subject device and primary predicate device are intended to provide remote patient monitoring with a wearable

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EpiMonitor

Features	EpiMonitor (Subject Device)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
	patients with epilepsy or at risk of having epilepsy, and for remote monitoring of physiological parameters which may provide supplementary support in the clinical management of epilepsy.		parameters in ambulatory adults in home-healthcare environments.	device, and to issue alerts to caregivers following detection of patterns that may be associated with a user experiencing a generalized tonic clonic seizure, and are therefore equivalent. The subject device and the secondary predicate are intended for remote monitoring of physiologic parameters to support clinical management, and are therefore equivalent.
Indications 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	The Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children aged 6 and up in home or healthcare facilities during periods of rest. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with generalized tonic clonic seizures in patients with epilepsy or at	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 home-healthcare environments.	The subject device and primary predicate device are intended to provide remote patient monitoring with a wearable device, and to issue alerts following detection of patterns that may be associated with a user experiencing a generalized tonic clonic seizure, and are therefore equivalent. The subject device and primary predicate device are indicated for

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EpiMonitor

Features	EpiMonitor (Subject Device)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
	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	risk of having epilepsy. When a seizure event is detected, Embrace sends a command to a paired wireless device that is programmed to initiate an alert to a designated caregiver. The System records and stores data from Accelerometer, EDA, and Temperature sensors for subsequent review by a trained healthcare professional.	The device supports the continuous monitoring of the following: ● Peripheral skin temperature, ● Electrodermal activity ● Blood Oxygen Saturation under no motion conditions ● 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	use in adults and children over 6 years old, and therefore have the same indicated age ranges. The subject device, primary and secondary predicate devices monitor physiological data from the user. This data is made available for healthcare professionals to view retrospectively. The subject device gathers Peripheral skin temperature and activity data as physiological parameters. These differ from the configuration on the predicate devices, as the primary predicate does not include activity data and the secondary predicate also includes blood oxygen saturation. The configuration of the subject device therefore incorporates features of both and can therefore be considered equivalent.

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Features	EpiMonitor (Subject Device)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
	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.		temperature monitoring, where monitoring temperature at the wrist is clinically indicated.	The subject device allows the user to temporarily change the detection sensitivity to either a low detection sensitivity setting or to turn it off. These have been introduced to allow the patient to participate in activities which previously may have triggered a false alarm. The differences in physiological parameters collected by the subject device as compared to the predicate devices do not impact the effectiveness or safety of the subject device, as SpO2 and activity data are not used as inputs to the algorithm used to detect patterns associated with generalized tonic-clonic seizures.
Target Population	Adults and Children aged 6 years and above	Adults and Children aged 6 years and above	Adult	The subject device and primary predicate are identical
Anatomical Site	Wrist	Wrist	Wrist	The subject device and the predicates are identical

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Features	EpiMonitor (Subject Device)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
Over the Counter or Rx	Rx	Rx	Rx	The subject device and the predicates are identical
Environment	Professional Healthcare Facilities & Home environment	Professional Healthcare Facilities & Home environment	Home environment	The subject device and primary predicate are identical. The subject device and the secondary predicate are intended for remote periodic monitoring of physiologic parameters to support clinical management, and are therefore equivalent.
User Interface	Layperson: Device screen with two side buttons Mobile device application (EpiMonitor) Caregiver(s): Voice call and SMS	Layperson: Device Top Cover with a central push button Mobile device application (Alert App) Caregiver(s): Voice call and SMS	Layperson: Device screen with two side buttons Mobile device application (Care App) Caregiver(s): Not Applicable	The subject device and primary predicate have minor differences in their interface, with a change in the button location from a central tap to two side buttons. This allows for a ink-white display to inform the user of the time and battery percentage as an aide for daily compliance. These do not affect clinical functionality which is the same as the primary predicate. The subject device and predicate devices use different companion applications, which represent

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Features	EpiMonitor (Subject Device)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
				differences in functionality available to the user such as sensitivity. This is discussed in a separate part of this table. The secondary predicate features identical hardware, and therefore is equivalent.
Energy Source	Battery	Battery	Battery	The subject device and the predicates are identical
Battery Type	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	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 predicates are identical
Patient contacting materials	Compliant to ISO 10993-1 Device housing: ● Polycarbonate ● Stainless steel ● Gorilla Glass 3 ● Thermoplastic Polyurethane Band:	Compliant to ISO 10993-1 Device housing: ● Anodized aluminum ● Polycarbonate ● Stainless steel Band (stretch variant): ● Polyester ● Polyurethane	Compliant to ISO 10993-1 Device housing: ● Polycarbonate ● Stainless steel ● Gorilla Glass 3 ● Thermoplastic Polyurethane Band:	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.

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Features	EpiMonitor (Subject Device)	Embrace (K181861) Primary Predicate	Empatica Health Monitoring Platform (K221282) Secondary Predicate	Analysis of differences
	● Silicone Rubber ● Stainless Steel	● Aluminum ● Nickel-free chrome plated buckle or Chromium Nitride PVD coated stainless steel Band (Vegan Leather variant): ● Microfiber polyurethane Buckle: ● Stainless steel, Chromium Nitride PVD coating	● Silicone Rubber ● Stainless Steel	
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 and includes two 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.	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.	N/A	The ”high” sensitivity mode of EpiMonitor is identical to the predicate device. The “low” sensitivity mode of the subject device is not available in the predicate. The performance of the ”low” sensitivity mode has been assessed through a longitudinal analysis of real-world data captured using the Embrace2. The secondary predicate does not feature seizure detection capabilities and therefore it is not applicable.

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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 EpiMonitor System, 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 testing included the following tests: ● Cytotoxicity ● Sensitization ● Irritation The EmbracePlus wearable device is considered skin surface contacting for a permanent duration (> 30 days).	Passed
Electrical safety testing	The wearable device component of the EpiMonitor System, 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 EpiMonitor System, EmbracePlus, was tested in accordance with International Standard IEC 60601-1-2 for EMC.	Passed
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
Usability testing	The EpiMonitor System has been 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 EpiMonitor System, 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 EpiMonitor System, EmbracePlus, has been tested in accordance with International Standard ISO 17664 and AAMI TIR 30 to assess device cleaning procedure.	Passed

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Test Name	Test Description	Results
Manual disinfection	The wearable device component of the EpiMonitor System, EmbracePlus, has been tested in accordance with ASTM E1837:2014 and AAMI TIR 12 to assess device low-level disinfection procedures.	Passed
Temperature measurement accuracy	The wearable device component of the EpiMonitor System, EmbracePlus, has been tested to confirm that 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 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
Activity and Motion	Testing comparing the performance of the Accelerometer Sensors in the EmbracePlus and Embrace Devices has been performed to demonstrate equivalent performance of the wearable device component of the EpiMonitor System, EmbracePlus, for activity data including with the predicate device.	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
Algorithm Performance (Clinical Testing)	No prospective clinical studies have been performed on the subject device. Two retrospective analyses of previously collected clinical data were conducted in order to evaluate the performance of the seizure detection algorithm referred to as EpiAlgo using the “Low Sensitivity” alerting threshold.	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 prospective 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).

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 Percentage 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
>21	843	14308	56389.1	0.25	0.22	0.30	0.29	0.26	0.33

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.