December 20, 2018

Empatica Srl
% Rakesh Lal
Consultant
Rakesh Lal
318 Rindge Ave 407
Cambridge, Massachusetts 02140

Re: K181861
Trade/Device Name: Embrace
Regulation Number: 21 CFR 882.1580
Regulation Name: Non-Electroencephalogram (EEG) Physiological Signal Based Seizure Monitoring System
Regulatory Class: Class II
Product Code: POS
Dated: November 20, 2018
Received: November 20, 2018

Dear Rakesh Lal:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K181861

Device Name
Embrace

Indications for Use *(Describe)*

The Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children age 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 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.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

510K Embrace Documentation

# 510(k) Summary

| | |
|---|---|
| Submitter Name: | Empatica S.r.l. |
| Submitter Address: | Via Stendhal 36<br>20144 Milano, Italy |
| 510(k) Submission Contact: | Rakesh Lal<br>817-734-8303 |
| Sponsor Contact Person: | Matteo Lai,<br>+393497888125 |
| Date Prepared: | December 19, 2018 |
| Device Trade Name: | Embrace |
| Device Common Name: | Non-EEG physiological signal based seizure monitoring system |
| Device Classification: | 21 CFR 882.1580, Product Code POS |
| Predicate Device: | Embrace, K172935 |
| Predicate Device Classification: | 21 CFR 882.1580, Product Code POS |
| Device Description: | The Embrace is a wearable biosensor device that can capture, store, and wirelessly transmit sensor data via Bluetooth to a paired remote device. Embrace runs an on-board algorithm to continuously process sensor data and make a decision about whether the data might indicate a generalized tonic clonic seizure (GTCS). The algorithm has been validated on data, labeled using the gold-standard video-Electroencephalogram (EEG) methodology designed by a group of epileptologists at a top level 6 epilepsy centers, from epilepsy patients experiencing GTCSs in hospital Epilepsy Monitoring Units. When a likely GTCS is detected, the Embrace sends a message to the Alert smartphone application, which initiates calls and texts to summon the attention of designated caregivers. The device also enables patients to manually record seizure events, and provides contextual information related to activity and sleep. |
| Indications for Use: | The Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children age 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 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. |

Substantial Equivalence: A comparison of Embrace to the predicate device is provided in the table below.

| Attribute | Embrace | Embrace (K172935) | Comparison |
|---|---|---|---|
| Intended Use | Non-EEG physiological signal based seizure monitoring system. | Non-EEG physiological signal based seizure monitoring system. | EQUIVALENT<br>Both devices have the same intended use. |
| Indications for use | The Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children age 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 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 Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults in the 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 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 Accelerometers, EDA, and Temperature for subsequent review by a trained healthcare professional. | Patient Population:<br>EQUIVALENT<br>Both devices are indicated for use on patients with epilepsy or at risk of having epilepsy. Embrace 2.0 is additionally indicated for use in children age 6 and up. This difference does not raise new questions of safety and effectiveness.<br><br>Healthcare Environment:<br>EQUIVALENT<br>Both the subject and predicate devices are indicated for use in the home and healthcare settings.<br><br>Seizure Type:<br>EQUIVALENT<br>Both devices are indicated to provide an alert to caregivers when they each detect GTC while the patient is at rest.<br><br>Effect on Clinical Outcome: EQUIVALENT<br>Both devices are indicated as an adjunct to other monitoring devices in the EMU. Neither of the devices is intended to guide therapy decisions. |
| Sensor Technology | Utilizes an electrodermal sensor to acquire Electrodermal Activity, | Utilizes an electrodermal sensor to acquire Electrodermal Activity, | EQUIVALENT |

| | | | |
|---|---|---|---|
| | and an accelerometer sensor to acquire movement data. | and an accelerometer sensor to acquire movement data. | |
| Software Level of Concern | Moderate | Moderate | EQUIVALENT |
| Data Communication | Communicates wirelessly to a smartphone application, which alerts the healthcare provider or caregiver in one or more ways (phone call, text message, etc.). | Communicates wirelessly to a smartphone application, which alerts the healthcare provider or caregiver in one or more ways (phone call, text message, etc.). | EQUIVALENT |
| Algorithm | Uses algorithms to analyze EDA and accelerometer data to detect patterns in the data that may be associated with GTC seizures. . | Uses algorithms to analyze EDA and accelerometer data to detect patterns in the data that may be associated with GTC seizures. | EQUIVALENT |
| Biocompatibility | All patient contacting parts are identical to the predicate device. | All patient contacting parts are tested to applicable tests in ISO 10993 (Cytotoxicity – ISO 10993-5, Sensitization – ISO 10993-10, and Skin Irritation – ISO 10993-10). | EQUIVALENT |
| Electrical Safety | All electrical and electronic parts are identical to the predicate device. | Electrical Safety testing performed to IEC 60601-1<br><br>Electromagnetic compatibility testing performed to IEC 60601-1-2 4th Edition | EQUIVALENT |
| Thermal Safety | Not applicable. The device does not generate any localized heat | Not applicable. The device does not generate any localized heat | EQUIVALENT |
| Chemical Safety | Not applicable. Patient is not exposed to any chemicals during use of the device | Not applicable. Patient is not exposed to any chemicals during use of the device | EQUIVALENT |
| Radiation Safety | Not applicable. Device does not use any ionizing radiation | Not applicable. Device does not use any ionizing radiation | EQUIVALENT |

Performance Testing:

Performance testing demonstrates that Embrace complies with IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, ISO 10993-5:2009, and ISO 10993-10:2010

Clinical Testing:

Clinical testing was performed to demonstrate the ability of the Embrace to function as an assessment aid for monitoring for seizure related activity in the intended population and for the intended use setting.

*Patients*:
141 patients diagnosed with epilepsy were admitted to the Epilepsy Monitoring Unit (EMU) for standard care were enrolled in the studies: 80 pediatrics, ages 6-21 years, median: 13 years; 61 adults, ages: 22-63 years, median: 39 years.

*Observed GTCS:*
31 EMU patients experienced a total of 54 generalized tonic clonic seizures (GTCSs) while 110 EMU patients did not experience any seizure. Every recorded seizure was classified as epileptic.

*Recorded data:*
141 patients provided overall 409 days (9,806 hours), with a median of 49.2 hours of data per patient of ACM and EDA measurements.

*Performance*:
On all the 141 patients, the Positive percent agreement (PPA) was found to be 0.9815 (53 out of 54 GTCSs detected), with a 95% confidence interval (CI) of [0.9028; 0.9702], relative to a panel of three readers, and the overall false alarm rate (FAR) was found to be 0.94 false alarms per 24 hours with a 95% confidence interval of [0.71, 1.21], corresponding to a mean FAR (average of FARs across patients) of 1.25. Table 1 and Table 2 report the PPA and the FAR separately on the adult patients (age 22 and up) and on pediatrics subgroups.

Table 1

| age | #patients | #GTCS | # detected GTCS | PPA | corrected PPA [1] | CI PPA | |
|---|---|---|---|---|---|---|---|
| 6-12 | 6 | 12 | 11 | 0.917 | 0.799 | 0.601 | 0.895 |
| 13-21 | 11 | 20 | 20 | 1 | 0.915 | 0.889 | 0.934 |
| 6-21 | 17 | 32 | 31 | 0.969 | 0.915 | 0.834 | 0.953 |
| >21 | 14 | 22 | 22 | 1 | 0.924 | 0.910 | 0.931 |

Table 2

| age | # patients | #FA | #days | Overall FAR | CI overall FAR | | Mean FAR | CI mean FAR | |
|---|---|---|---|---|---|---|---|---|---|
| 6-12 | 39 | 89 | 67.02 | 1.33 | 0.82 | 1.98 | 1.79 | 0.99 | 2.73 |
| 13-21 | 41 | 129 | 93.98 | 1.37 | 0.75 | 2.17 | 1.47 | 0.72 | 2.41 |
| 6-21 | 80 | 218 | 161 | 1.35 | 0.92 | 1.87 | 1.63 | 1.06 | 2.28 |
| >21 | 61 | 165 | 247.6 | 0.67 | 0.43 | 0.95 | 0.76 | 0.43 | 1.17 |

[1] A conservative correction was applied to PPA to account for extreme probability values (PPA ~= 1) and the presence of multiple seizures for some patients (Chew, The American Statistician, 25(5), 47-50, 1971; Saha et al, Int J Biostat., 12(2), 2016).

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|---|---|
| Conclusion: | The subject device has the same intended use as the predicate device, and differences in technological characteristics do not raise different questions of safety and effectiveness. On this basis, Embrace is substantially equivalent to the legally marketed predicate device. |