March 7, 2025

EpiWatch, Inc.
% Brittany Valdez Nava
Regulatory Specialist
Healthcare Innovation Catalysts, Inc.
8024 Summer Mill Court
Bethesda, Maryland 20817

Re: K243515
Trade/Device Name: EpiWatch Monitoring System
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: February 5, 2025
Received: February 5, 2025

Dear Brittany Valdez Nava:

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,

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)*
K243515

Device Name
EpiWatch Monitoring System

Indications for Use *(Describe)*
The EpiWatch Monitoring System is a prescription, software-only mobile medical application intended for use with a compatible wrist-worn device as an adjunct to seizure monitoring of adults and children ages 5 and up in home or healthcare settings during periods of rest.

The EpiWatch Monitoring System continuously records, stores, displays, and transfers data from the compatible wrist-worn device's built-in physiological-based sensors to support review by healthcare professionals, and people with epilepsy (PWE) or at risk of epilepsy.

When the EpiWatch Monitoring System detects and logs physiological patterns associated with generalized tonic-clonic seizures (TCS), the EpiWatch Monitoring System application alerts the user and/or the identified caregiver(s) to notify of detected possible seizure events.

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.

1.0 510(K) SUMMARY

This 510(k) summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

1.1 Submitter's Information

Company Name: EpiWatch, Inc.

Address:
c/o Johns Hopkins Technology Ventures
1812 Ashland Ave, Suite 110
Baltimore, Maryland, 21205
United States

Company Contact:
Teresa Prego
Chief Executive Officer
EpiWatch, Inc.
c/o Johns Hopkins Technology Ventures
1812 Ashland Ave, Suite 110
Baltimore, Maryland, 21205
United States
Phone: +1 (339) 206-1833
Email: tprego@epiwatch.com

Official Correspondent:
Brittany Valdez Nava, MRSc.
Regulatory Specialist
Healthcare Innovation Catalysts, Inc.
8024 Summer Mill Court
Bethesda, MD 20817

Date prepared: November 12, 2024

1.2 Subject Device Name

Trade Name: EpiWatch Monitoring System

Common Name: EpiWatch Monitoring System

Regulation Name: Non-electroencephalogram (EEG) physiological signal-based seizure monitoring system

Regulation Number: 21 CFR 882.1580

Device Class: Class II

Product Code: POS

Product Code Name: Physiological Signal-Based Seizure Monitoring System

510(k) Review Panel: Neurology

1.3 Legally Marketed Predicate/Reference Devices

1.3.1 Empatica Embrace

The primary predicate device for the EpiWatch Monitoring System is the Embrace cleared under K181861.

510(k) Number	K181861
Trade Name:	Embrace
Common Name:	Non-electroencephalogram (EEG) physiological signal-based seizure monitoring system
Regulation Name:	Non-electroencephalogram (EEG) physiological signal-based seizure monitoring system
Regulation Number:	21 CFR 882.1580
Device Class:	Class II
Product Code:	POS
Product Code Name:	Physiological Signal-Based Seizure Monitoring System
510(k) Review Panel:	Neurology

1.3.2 Empatica EpiMonitor

A reference device for the EpiWatch Monitoring System is the EpiMonitor cleared under K232915.

510(k) Number	K232915
Trade Name:	EpiMonitor
Common Name:	Non-electroencephalogram (EEG) physiological signal-based seizure monitoring system
Regulation Name:	Non-electroencephalogram (EEG) physiological signal-based seizure monitoring system
Regulation Number:	21 CFR 882.1580
Device Class:	Class II
Product Code:	POS
Product Code Name:	Physiological Signal-Based Seizure Monitoring System
Subsequent Product Code(s):	FLL, LEL
510(k) Review Panel:	Neurology

1.4 Device Description

1.4.1 Brief Description of the Device

The EpiWatch Monitoring System is a non-electroencephalogram (non-EEG) physiological signal-based seizure monitoring system. It is similar to other legally-marketed non-electroencephalogram (non-EEG) physiological signal-based seizure monitoring systems.

The EpiWatch Monitoring System consists of a software-only mobile medical application intended for use with a compatible wrist-worn device as an adjunct to seizure monitoring of adults and children ages 5 and up.

EpiWatch Monitoring System is a software platform composed of:

- A compatible wrist-worn device, (e.g. an Apple Watch)
- A mobile application running on smartphones called the "EpiWatch Monitoring System App".

The wrist-worn device continuously collects raw data via specific sensors, and feeds consolidated physiological data to the EpiWatch app via APIs. Utilizing a proprietary algorithm, EpiWatch analyzes and assesses the physiological data and determines if there is suspected generalized tonic-clonic seizure activity (TCS). The EpiWatch algorithm has been validated through testing, using the gold-standard video electroencephalogram (vEEG) methodology designed by a group of epileptologists at a top level 4 epilepsy center, of epilepsy patients experiencing TCSs in hospital Epilepsy Monitoring Units.

When a likely TCS is detected, the EpiWatch Monitoring System App communicates to the EpiWatch Cloud which initiates, through an external provider, a voice call, email and an SMS text message (notification parameters are set by the user at contact setup) to summon the attention of caregiver(s).

In addition to initiating alerts, the EpiWatch app also continuously receives all the sensor data collected by the wrist worn device. The EpiWatch App is also responsible for transmitting—over a cellular data plan or Wi-Fi connection—the API data, device information, and computed physiological parameters to the EpiWatch Cloud for further review and storage, which allows seizure reports and other features added to alerting. It also provides necessary information about the state of the system.

1.4.2 Indications for Use

The EpiWatch Monitoring System is a prescription, software-only mobile medical application intended for use with a compatible wrist-worn device as an adjunct to seizure monitoring of adults and children ages 5 and up in home or healthcare settings during periods of rest.

The EpiWatch Monitoring System continuously records, stores, displays, and transfers data from the compatible wrist-worn device’s built-in physiological-based sensors to support review by healthcare professionals, and people with epilepsy (PWE) or at risk of epilepsy.

When the EpiWatch Monitoring System detects and logs physiological patterns associated with generalized tonic-clonic seizures (TCS), the EpiWatch Monitoring System application alerts the user and/or the identified caregiver(s) to notify of detected possible seizure events.

1.4.3 Environment of Use

The EpiWatch Monitoring System is intended for use in professional healthcare facilities and home environments.

1.5 Key Performance Characteristics

The key performance specifications and characteristics of the EpiWatch Monitoring System are outlined in **Table 1**.

Table 1: Key Performance Characteristics

Attribute	Specification/Characteristic
Intended Use	The EpiWatch Monitoring System is intended as a noninvasive prescription device that acts as an adjunct for the detection and alerting of possible generalized tonic-clonic seizures in patients with epilepsy or at risk of having generalized tonic-clonic seizures, and for remote monitoring of physiological parameters which may provide supplementary support in the clinical management of epilepsy.
Indications for Use	The EpiWatch Monitoring System is a prescription, software-only mobile medical application intended for use with a compatible wrist-worn device as an adjunct to seizure monitoring of adults and children ages 5 and up in home or healthcare settings during periods of rest. The EpiWatch Monitoring System continuously records, stores, displays, and transfers data from the compatible wrist-worn device's built-in physiological-based sensors to support review by healthcare professionals, and people with epilepsy (PWE) or at risk of epilepsy. When the EpiWatch Monitoring System detects and logs physiological patterns associated with generalized tonic-clonic seizures (TCS), the EpiWatch Monitoring System application alerts the user and/or the identified caregiver(s) to notify of detected possible seizure events.
Anatomical Site	Designed to be worn on the wrist
Measurement Device/Method	The EpiWatch Monitoring System utilizes a compatible wrist-worn device (see Compatibility with Intended Platform) that can capture and wirelessly transmit sensor data via Bluetooth to a paired remote device.
Compatibility with Intended Platforms	Compatible wrist-worn devices: • Apple Watch: watchOS version 10 or higher Smartphones: • iOS version 17 or higher
Principle of Operation (Seizure Detection Algorithm)	Uses algorithm to analyze physiological-based sensor data to detect patterns in the data that may be associated with TCS.
Sensor Technology	Utilizes compatible wrist-worn device's built-in physiological-based sensors to acquire physiological data.
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.).

1.6 Comparision of Key Technological Characteristics with the Predicate Device(s)

1.6.1 Embrace

The EpiWatch Monitoring System (subject device) and the Embrace (predicate device) have equivalent intended use and indications for use. The subject and predicate devices have similar designs, configurations, technological characteristics, and principles of operation.

These devices have the following similar features:

- **Wearer and Caregiver Monitoring**: Provides real-time monitoring capabilities for both the wearer of the EpiWatch Monitoring System device and their designated caregivers. This function allows the wearer and caregiver(s) to control and customize the real-time monitoring settings according to their needs and preferences.
- **Event Detection and Logging:** Handles the logging of all detected events, including real-time detections and detections for intermittent retrospective review. The logged data includes timestamp, event type, duration, and any other relevant parameters associated with the detected event.
- **Alerting:** Alerts users and caregivers when a possible seizure event is detected.
    - Includes the ability to cancel alerts if a false alarm occurs, and ability to notate if a false alarm has occurred.
    - Includes the ability to notify caregivers that the user is "OK" after an alert has been sent
- **Data Recording, Storage, Display and Transfer:** Continuously records, stores, and wirelessly transfers sensor data via Bluetooth to a paired remote device.
    - Generates a report of detected seizure events that the user and those assigned can review

Main Differences between the EpiWatch Monitoring System and Embrace [K181861]

Regarding the physiological sensor, the Embrace collects physiological data from their proprietary sensor technology (EDA and accelerometer) embedded in their proprietary wrist-worn device, while the EpiWatch Monitoring System relies on a third-party Off-The-Shelf wrist-worn hardware platform device (such as the Apple Watch) with embedded physiological sensors.

- This does not impact safety or effectiveness of the EpiWatch Monitoring System, as EpiWatch regularly performs compatibility assessments to the compatible wrist worn hardware platform to ensure that the physiological sensors utilized are within specification for the EpiWatch Monitoring System.

The difference in technological characteristics has been evaluated through clinical testing. The results of these studies verify that these differences do not raise new or different questions of safety and effectiveness when the EpiWatch Monitoring System is used as intended.

1.6.2 EpiMonitor

The EpiWatch Monitoring System (subject device) and the EpiMonitor (reference device) have equivalent intended use and indications for use. The subject and predicate devices have similar designs, configurations, technological characteristics, and principles of operation.

Both the EpiWatch Monitoring System and the EpiMonitor utilize the Embrace as the primary predicate device.

Main Differences between the EpiWatch Monitoring System and the EpiMonitor [K232915]

The primary difference between the reference device (EpiMonitor) and the subject device (the EpiWatch Monitoring System) is the difference in sensitivity settings. The reference device (EpiMonitor [K232915]) incorporates two detection sensitivity modes to address the challenge associated with the relatively high FAR observed in the predicate (Embrace [K181861] during active periods:

“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 incident.”

The EpiWatch Monitoring System exhibits a 10-fold reduction in FAR when compared to the predicate, while maintaining an equivalent Positive Percent Agreement (PPA). The EpiWatch Monitoring system achieves this high level of performance without the need to decrease sensitivity during non-rest activities, and without the need for users to manually set their activity level. The EpiWatch Monitoring system also achieves this level of performance through continuous monitoring without removing or blanking data from periods of activity or otherwise restricting methodology to periods of rest.

1.7 Performance Data

1.7.1 Human Factors Validation Testing

Human Factors validation testing performed on the EpiWatch Monitoring System found no impact on the safe and effective use of the device. EpiWatch, Inc. concludes that the system is safe and effective for the intended users, uses, and use environments.

1.7.2 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.

Additionally, software verification information within this submission is provided in accordance with the following FDA guidance documents:

- Guidance for Off-The-Shelf Software Use in Medical Devices (11 August 2023)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (27 September 2023)

1.7.3 Cybersecurity

Cybersecurity documentation has been provided with this application as recommended by the FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions ". All the EpiWatch Monitoring System software components underwent appropriate cybersecurity assessment and testing.

1.7.4 Animal Studies

No animal studies were performed on this device.

1.7.5 Clinical Studies

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

EpiWatch conducted a single arm, blinded study of 242 subjects (total 16,189 hours) to evaluate the performance of the EpiWatch algorithm for detecting TCSs. Potentially eligible subjects were identified among the in-patient population in Epilepsy Monitoring Units (EMU) at six geographically diverse trial sites. EMU patients with Lennox-Gastaut syndrome or Rett syndrome were excluded from analysis. Typical duration of enrollee participation ranged from 0.42-11.25 days, based on the length of each subject's stay in the EMU. The length of stay was not influenced by enrollment in the study. Subjects included a broad demographic range of children and adults (See **Table 2**).

There were no serious adverse events (SAEs) or adverse device effects.

Table 2: Demographic Distribution

Subject Total : N-242	
Age	**Mean**: 22.68 **Standard Deviation**: 14.2 **Median**: 18 **Min**: 5 **Max**: 76
	N= (%)
Age Group (years)	
<13	55 (22.7)
12-21	92 (38.0
>21	95 (39.3)
Gender	
Female	131 (54.1)
Male	111 (45.4)
Race	
White	162 (66.9)
African American	60 (24.8)
Asian	5 (2.1)
Native American	0 (0.0)
Pacific Islander	1 (0.4)
Other	14 (5.8)
Not Reported	1(0.41)
Ethnicity	
Hispanic	21 (8.7)
Non-Hispanic	202 (83.5)
Not Reported	19 (7.8)

1.7.6 Sensitivity (Positive Percent Agreement (PPA))

The 242 study subjects had 16,189 hours of study monitoring. They had 47 TCSs confirmed by the central panel; 46 (98%) of these were detected by the EpiWatch Monitoring System (**Table 3**). The EpiWatch PPA (sensitivity) was

- 0.98, adjusted for all age groups;
- 1.0 for ages 5-12 years,
- 0.95 for ages 13-21 years and
- 1.0 for adults (>21 years).

1.7.7 False Alarm Rate (FAR)

There were 56 false alarms of which 20 were seizures with motor signs. This resulted in a FAR for detecting TCSs at 0.083 per 24-hour period. This point estimate equals an estimated rate of one false alarm in 12.4 days. The age groups all had similarly low FARs. (See **Table 4**). More than 1/3 of the false alarms, however, were seizures with motor signs.

The PPA and FAR details are included in the following tables:

Table 3: PPA Results

Age Group (years)	#patients	#patients with TCS	Total TCS	Detected TCS	PPA	Corrected PPA[1]	CI PPA	
5-12	55	3	6	6	1.000	0.800	0.758	0.842
13-21	92	15	10	19*	0.950	0.875	0.819	0.931
22+	99	19	21	21	1.000	0.920	0.878	0.962
All	242	37	47	46	0.979	0.941	0.910	0.972

*The single undetected TCS was in an adolescent whose watch arm was restrained by a caregiver.

Table 4: FAR Results

Age Group (years)	#patients	#False Alarms	# days	Overall FAR	CI Overall FAR	
5-12	55	8	112.56	0.071	0.019	0.139
13-21	92	22	225.48	0.098	0.048	0.156
22+	99	26	336.51	0.077	0.020	0.154
All	242	56	674.55	0.083	0.048	0.127

1.7.8 Positive Predictive Value (PPV)

Positive Predictive Value is defined as the number of true positive detections divided by the sum of the true positives plus false positives (PPV= TP/(TP+FP)).

There were 102 positive detections predicted by the device, with 46 of them being true positives and 56 of them being false positives. This resulted in a PPV of 45.10%.

[1] A conservative correction was applied to PPA and its confidence limits to account for extreme probability values (PPA~=1) and the presence of multiple seizures for some patients by the method of Saja et al. (2016) using the GEE2 version of the Wilson Score method to match the adjusted data of the predicate (Saha et al, Int J Biostat., 12(2), 2016)

1.8 Conclusions

Based on above discussion and enclosed sections regarding substantial equivalence to the predicate device, EpiWatch, Inc. concludes that the EpiWatch Monitoring System is substantially equivalent to its predicate device, Empatica Embrace [K181861], and its reference device, Empatica EpiMonitor [K232915], and does not raise any new or different questions of safety or effectiveness.