July 12, 2025

LivAssured BV
Jolanda Oorthuizen
Quality Assurance and Regulatory Affairs Manager
Schipholweg 103
2316 XC
Leiden, Netherlands

Re: K243199
Trade/Device Name: NightWatch+ US
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: June 11, 2025
Received: June 11, 2025

Dear Jolanda Oorthuizen:

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,

Jay R. Gupta -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243199

Device Name

NightWatch+ US

Indications for Use *(Describe)*

The NightWatch+ US is a prescription only device that is indicated for use as an adjunct to seizure monitoring of children age 4 till 16 diagnosed with epilepsy having Nocturnal Epileptic Major Motor Seizures which includes tonic-clonic (TC), tonic (if clustered or prolonged >30 seconds), hyperkinetic and TC-like seizures, in home or residential facilities during periods of rest. The Sensor of the device is worn on the upper arm and measures heart rate and motion data to detect patterns that may be associated with nocturnal epileptic motor seizures in patients with epilepsy. When a seizure event is detected by the Sensor of the NightWatch+ US, it sends a command to the paired wireless alarm station of the NightWatch+ US that is programmed to initiate an alarm to a designated caregiver. The system records and stores data from seizure events. The data can be viewed by the user in a cloud based data portal. The NightWatch+ US is not intended to diagnose specific seizure types.

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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510(k) Summary

NightWatch+ US

LivAssured

510(K) SUMMARY

The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.
This summary was prepared on the 10th of July 2025.

Submitter's Information

Company Name	LivAssured BV
Company Address	Schipholweg 103 2316 XC, Leiden The Netherlands
Contact Person	Jolanda Oorthuizen
Telephone	+3185 0601252
Email	Jolanda@nightwatch.nl

Subject Medical Device

Device Name	NightWatch+ US
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

Legally Marketed Predicate Device

510(k) Number	181861
Device Name	Embrace
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

Device Description

NightWatch+ US consists of a sensor worn during sleep on the biceps of the upper arm and an alarm station. The sensor consists of a heart rate sensor using PPG (photoplethysmography), a ACC (Accelerometry) movement sensor, and a microprocessor. The microprocessor processes the data from the sensors using a detection algorithm which detects if the sensor readings match pre-programmed parameters that are associated with nocturnal epileptic major motor seizures. When a nocturnal epileptic major motor seizures is detected, the seizure alarm is triggered and transferred from the sensor to the accompanying alarm station which alarms the caregiver by a sound and a blinking LED light. The seizure alarms data can be transferred from the alarm station, using an ethernet connection, to a database in the cloud to be viewed a web-based interface called NightWatch Portal to be able to monitor seizure frequency overtime.

Indication for use

The NightWatch+ US is a prescription only device that is indicated for use as an adjunct to seizure monitoring of children age 4 till 16 diagnosed with epilepsy having Nocturnal Epileptic Major Motor Seizures which includes tonic-clonic (TC), tonic (if clustered or prolonged >30 seconds), hyperkinetic and TC-like seizures, in home or residential facilities during periods of rest. The Sensor of the device is worn on the upper arm and measures heart rate and motion data to detect patterns that may be associated with nocturnal epileptic motor seizures in patients with epilepsy. When a seizure event is detected by the Sensor of the NightWatch+ US, it sends a command to the paired wireless alarm station of the NightWatch+ US that is programmed to initiate an alarm to a designated caregiver. The system records and stores data from seizure events. The data can be viewed by the user in a cloud based data portal. The NightWatch+ US is not intended to diagnose specific seizure types.

Substantial Equivalence

A comparison of NightWatch+ US to the predicate device is provided in the table below

Attribute	NightWatch+ US (subject device)	Embrace K181861 (predicate device)	Comparison
Intended Use	Non-EEG physiological signal based seizure monitoring system.	Non-EEG physiological signal based seizure monitoring system.	EQUIVALENT Both devices have the same intended use.
Indications for use	The NightWatch+ US is a prescription only device that is indicated for use as an adjunct to seizure monitoring of children age 4 till 16 diagnosed with epilepsy having Nocturnal Epileptic Major Motor Seizures which includes tonic-clonic (TC), tonic (if clustered or prolonged >30 seconds), hyperkinetic and TC-like seizures, in home or residential facilities during periods of rest. The Sensor of the device is worn on the upper arm and measures hearth rate and motion data to detect patterns that may be associated with nocturnal epileptic motor seizures in patients with epilepsy. When a seizure event is detected by the Sensor of the NightWatch+ US, it sends a command to the paired wireless alarm station of the NightWatch+ US that is programmed to initiate an alarm to a designated caregiver. The system records and stores data from seizure events. The data can be viewed by the user in a cloud based data portal. The NightWatch+ US is not intended to diagnose specific seizure types.	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.	<u>Patient Population:</u> EQUIVALENT The devices are indicated for use on patients with epilepsy. Both NightWatch+ US and Embrace are indicated for pediatric population. NightWatch+ US is indicated for use in children age 4 till 16 years and Embrace is indicated for children 6 years and up. The difference in age groups does not raise any new safety or performance concerns. <u>Healthcare Environment:</u> EQUIVALENT Both the subject and predicate devices are indicated for use in the home. Embrace is also indicated for use in healthcare settings. The more limited healthcare environment for the subject device does not raise any new safety or performance concerns. <u>Way of notification caregiver:</u> EQUIVALENT Both do have a paired wireless device that is programmed to initiate an alert to a designated caregiver. In case of Nightwatch+ US there is a separate alarm station, in case of Embrace an app is used. This difference does not raise any new safety or performance concerns. as both devices are compliant to the FCC requirements of CFR no. 47, Part 15 <u>Seizure Type:</u> EQUIVALENT Both devices are indicated to provide an alert to caregivers when they each detect Tonic-Clonic seizures. Additionally NightWatch+ US is intended to alert for tonic (if cluster or prolonged >30 seconds),

Attribute	NightWatch+ US (subject device)	Embrace K181861 (predicate device)	Comparison
			hyperkinetic and TC-like seizures. This does not raise any new safety or performance concerns as NightWatch+ was extensively validated in a phase 4 peer reviewed scientific clinical study for these seizure types. Both devices monitor physiological signals while the patient is at rest.
			Over The Counter or RX EQUIVALENT The subject device and the predicate are both prescription devices
Classification	Class II 21 CFR 882.1580 Non-EEG physiological signal-based seizure monitoring system	Class II 21 CFR 882.1580 Non-EEG physiological signal-based seizure monitoring system	EQUIVALENT
Product Code	POS	POS	EQUIVALENT
Sensor application	The Sensor of the NightWatch+ US is worn on the upper arm with an elastic strap	The embrace watch is worn on the wrist with an elastic strap.	EQUIVALENT Both devices are worn using an elastic strap on the upper limb.
Materials			
Materials and Biocompatibility	All patient contacting parts are tested to applicable tests in EN ISO 10993-1:2018 (Cytotoxicity – ISO 10993-5:2009, Sensitization - ISO 10993- 10:2021, and Skin Irritation – ISO 10993-23:2021).	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 Both devices have patient contacting parts that come into contact with intact skin for a duration that may exceed 24 hours. Both devices meet the requirements of ISO 10993. See chapter 4.3 non clinical testing. .
Technical Specification			
Sensor technology	Utilizes an Photoplethysmogram (PPG) sensor to acquire Heart rate and an accelerometer sensor to acquire movement data.	Utilizes an electrodermal sensor to acquire Electrodermal Activity, an accelerometer sensor to acquire movement data and a temperature sensor.	EQUIVALENT The difference in type of sensors does not raise different questions of safety and effectiveness. PPG sensors and accelerometer sensors are widely used in many kinds of consumer technology and are concerned generally safe.
Data communication	The NightWatch+ US Sensor communicates wirelessly to the NightWatch+ US Alarm station which alerts the	The Embrace device communicates wirelessly to a smartphone	EQUIVALENT Both systems utilize wireless communication between the sensor and a alarm station or

Attribute	NightWatch+ US (subject device)	Embrace K181861 (predicate device)	Comparison
	healthcare provider or caregiver with an audible alarm and lights The NightWatch+ US is compliant to FCC Rules: Code of Federal Regulations (CFR) no. 47, Part 15	application, which alerts the healthcare provider or caregiver in one or more ways (phone call, text message, etc.). The Embrace is compliant to FCC Rules: Code of Federal Regulations (CFR) no. 47, Part 15	app, and use technologies to alert the caregiver like audible alarms. Both devices are compliant to the FCC requirements of CFR no. 47, Part 15. See chapter 4.3 non-clinical performance testing.
Data storage	Data of the device and seizure frequency can be stored on a cloud based platform for later viewing.	Data of the device and seizure frequency is stored on a cloud based platform for later viewing.	EQUIVALENT For both devices data of the device and seizure frequency can be stored on a cloud based platform for later viewing.
Energy Source Wearable	Battery	Battery	EQUIVALENT The Energy Source of the Wearable for both devices is a battery
Battery Type	Rechargeable Lithium-Ion	Rechargeable Lithium-Ion	EQUIVALENT For both devices the battery in the wearable is a Rechargeable Lithium-Ion
Algorithm	Uses algorithms to analyze PPG and accelerometer data to detect patterns in the data that may be associated with tonic-clonic, tonic (if cluster or prolonged), myoclonic (if clustered) or hyperkinetic seizures	Uses algorithms to analyze EDA and accelerometer data to detect patterns in the data that may be associated with generalized tonic-clonic seizures	EQUIVALENT The difference in the algorithms do not raise different questions of safety and effectiveness. The same questions of safety and effectiveness regarding performance of the algorithms (Sensitivity and False Alarm Rate) apply to all seizure detection devices.
Electrical Safety	Electrical Safety testing performed to IEC 60601-1 Electromagnetic compatibility testing performed to IEC 60601-1-2	Electrical Safety testing performed to IEC 60601-1 Electromagnetic compatibility testing performed to IEC 60601-1-2	EQUIVALENT Both devices underwent Electrical Safety testing performed to IEC 60601-1 and Electromagnetic compatibility testing performed to IEC 60601-1-2
Thermal Safety	Not applicable. The device does not generate any localized heat	Not applicable. The device does not generate any localized heat	EQUIVALENT Not applicable. Both devices do not generate any localized heat
Radiation Safety	Not applicable. Device does not use any ionizing radiation	Not applicable. Device does not use any ionizing radiation	EQUIVALENT Not applicable. Both devices do not use any ionizing radiation
Sterility	Not applicable. Device is not	Not applicable. Device is	EQUIVALENT

Attribute	NightWatch+ US (subject device)	Embrace K181861 (predicate device)	Comparison
	sterilized	not sterilized	Not applicable. Both devices are not sterilized.
Packaging method	No special packaging requirements	No special packaging requirements	EQUIVALENT No special packaging requirements

Table 1: Substantial equivalence comparison

Performance testing

Non-Clinical testing

The following non-clinical testing was conducted which support a determination of substantial equivalence to the predicate. The non-clinical tests included:

Standards	Description	Certificate or laboratory test report	FDA recognition number
IEC 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	TD-NWP-85: Certificate SIQ SI-10555	19-49
IEC 60601-1-2:2014 +A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	TD-NWP-81 : Certificate SIQ SI-10670 TD-NWP-82: Test Report: T251-0707/23	19-36
ETSI EN 301 489-1 V2.2.3:2019	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements	TD-NWP-82: Test Report: T251-0707/23	-
ETSI EN 301 489-6 V2.2.1: :2019	ElectroMagnetic Compatibility (EMC) Standard For Radio Equipment And Services; Part 6: Specific Conditions For Digital Enhanced Cordless Telecommunications (DECT) Equipment	TD-NWP-82: Test Report: T251-0707/23	-
IEC 60601-1-6:2010+A1:2013+A2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential	TD-NWP-85: Certificate SIQ SI-10555	5-132

Standards	Description	Certificate or laboratory test report	FDA recognition number
	performance- Collateral standard: Usability		
IEC 60601-1-8:2006+A1:2012+A2:2020	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	TD-NWP-85: Certificate SIQ SI-10555	5-131
IEC 60601-1-11:2015+A1:2020	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	TD-NWP-85: Certificate SIQ SI-10555	19-38
47 CFR 1.1310	Radiofrequency radiation exposure limits.	TD-NWUS-23: Test Report No: 1-6175-23-02-04_TR1-R01	-
47 CFR Part 15, Subpart B	Equipment authorization of unintentional radiators.	TD-NWUS-12: Certificate SIQ C251-0059/24	-
47 CFR Part 15, Subpart D	Unlicensed Personal Communications Service Devices	TD-NWUS-19: FCC ID: 2BGSP-NWP1 TD-NWUS-22: FCC ID: Y82-SC14S	-
ETSI EN 301 406 V2.2.2 (2016-09)	Digital Enhanced Cordless Telecommunications (DECT); Harmonised Standard for access to radio spectrum; Part 1: DECT, DECT Evolution and DECT ULE	TD-NWP-87: Test report: CETECOM nr: 1-6175_23-01-06 & CETECOM nr: 1-6175_23-01-07	-
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	TD-NWUS-10: 24-74-1 Biological Risk Assessment of NightWatch + US according to EN ISO 10993-1:2018 and FDA Guidance document "Use of	2-258

Standards	Description	Certificate or laboratory test report	FDA recognition number
		International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process" dated 8. September 2023	
ISO 10993- 10:2021	Biological evaluation of medical devices- Part 10: Tests for skin sensitization	TD-NWP-103: 23-109-2-SP.01 Sensitization	2-296
ISO 10993-5:2009	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	TD-NWP-101: Test Report 23-54-1-SP.01 Cytotoxicity	2-245
ISO 10993-23:2021	Biological evaluation of medical devices- Part 23: Tests for irritation	TD-NWP-104: Test Report: 23-109-3-SP.01 Irritation	2-291

Table 2: Non-clinical testing of the subject device NightWatch+ US

Clinical testing

NightWatch+ US is a US-targeted version of a NightWatch+, which is a class IIa medical device under the Medical Device Regulation 2017/745 in Europe. Its predecessor NightWatch has been on the European market since 2018. The seizure detection method, algorithms and components used for seizure detection are identical in both NightWatch, NightWatch+ and NightWatch+ US.

The clinical study used for the clearance of the NightWatch+ US for the indicated user group of Children age 4-16 years old is the study of van Westrhenen et al. 2023, a phase 4, multicenter, prospective, video-controlled, in-home study.

1. van Westrhenen, R. Lazeron, J. van Dijk, F. S. S. Leijten and R. D. Thijs, "Multimodal nocturnal seizure detection in children with epilepsy: A prospective, multicenter, long-term, in-home trial," Epilepsia, vol. 64, pp. 2137-2152, 2023.

In this study 53 children aged 4–16 years were included with ≥1 weekly nocturnal epileptic major motor seizure, living at home. Performance for nocturnal epileptic major motor seizures was determined. **The study sample size was determined based on an 80% sensitivity estimate, and performance goals or acceptance criteria for other endpoints were not defined.**

Demographics:

N=53	
Sex	
Male, n (%)	29 (55%)
Female, n (%)	24 (45%)
Age, years, Mean (range)	9.7±3.6 (4-16)
Learning disability	
Yes, n (%)	36(68%)
No, n (%)	17(32%)
Epilepsy etiology	
Structural, n (%)	13 (25%)
Genetic, n (%)	20 (38%)
infectious, n (%)	1 (1%)
Metabolic, n (%)	0
Immune, n (%)	0
Unknown, n (%)	19(36%)

Table 3: Demographics of participants in the van Westrhenen et al. 2023 study

Results: 2310 nights (28173 h), including 552 nocturnal epileptic major motor seizures were analyzed.

	Overall. Nocturnal Epileptic Major motor	Tonic Clonic (TC)	Tonic (>30 sec)	Hypermotor	Other major (TC-like seizures)
nr of patients	51	20	11	7	23
nr of seizures	552	204	30	48	270
nr of seizures detected	492	191	16	40	245
PPA point estimate mean sensitivity	90%	98%	71%	58%	87%
PPA 95% CI lower	84%	94%	43%	17%	75%
PPA 95% CI upper	96%	100%	100%	99%	100%
Overall sensitivity	89%	94%	53%	83%	91%

Table 4: Performance metrics, Sensitivity, of the van Westrhenen et al. 2023 study

False alarms rate (FAR) total	
Total false alarms	1642
FAR/h mean	0,07
FAR/h 95% CI Lower	0,04
FAR/h 95% CI upper	0,10
Overall FAR/h	0,06

Table 5: Performance metrics, FAR, of the van Westrhenen et al. 2023 study

In the following table a summary of the study results can be found and equivalence to the predicate device study results is discussed:

	Westrhenen et al. 2023[1]	K181861 Embrace clearance by FDA for Children 6 years and up	Equivalence?
Reference Standard	Video	Video-EEG	EQUIVALENT, Video is an equally robust reference standards to Video-EEG provided the whole dataset is reviewed for inferring the reference standard as recognized by the International League Against Epilepsy (ILAE) [2] Trained trial nurses annotated all events (generated NightWatch alarms, video alarms, and caregivers' seizure diary) using the video recordings while blinded for alarm type and NightWatch sensor data (HR and movement). In case of discrepancies (when the recorded night was annotated by one nurse, but screened by another) or doubt, the trial nurses consulted one of the principal investigators (R.D.T., R.H.C.L.) for a final decision. The principal investigators (R.D.T., R.H.C.L.) double checked a random sample of 5% of the annotations Additionally, trial nurses retrospectively analyzed video tracings with a previously validated automated video- based seizure detection algorithm. Trained trial nurses also fully screened the video of 5% of all nights for missed seizures; every video was screened by one nurse. In total, 1402 h (5%) of all recorded nights were randomly screened, ranging from half a night to four full nights per participant.
Data analysis method. Patient -level analysis versus event-level analysis	Event-level analysis and Patient -level analysis	Event-level analysis	EQUIVALENT, Van Westrhenen et al. 2023 used patient-level analysis because it provides a more accurate reflection of device performance across individuals, rather than being skewed by outliers with many events. This approach is valid and meaningful due to the high number of events per participant, enabled by the prolonged in-home monitoring period. In contrast, the predicate device study included relatively few events among a small group of patients, making a robust patient-level analysis less feasible. More-over, event-level analysis can distort overall performance metrics, especially when a large proportion of events originates from a small subset

	Westrhenen et al. 2023[1]	K181861 Embrace clearance by FDA for Children 6 years and up	Equivalence?
			of participants. Nevertheless, both approaches were included in the publication of van Westrhenen et al. 2023. The difference in analysis method does not raise new concerns for performance or safety compared to the predicate device
Number of included children	53 children (age 4-16 years)	80 children (ages 6- 21 years)	EQUIVALENT, The difference in age group does not raise new concerns for performance or safety compared to the predicate device. Both studies include enough participants
Number of seizures detected Total for children	**33** children experienced in total **552** nocturnal epileptic major motor seizures of which **204** TC seizures	**17** children experienced in total **32** TC seizures	EQUIVALENT, No new concerns for performance or safety compared to the predicate device. Westrhenen et al. 2023 included more seizures than the study of the predicate device.
Number of hours data recorded	All 53 patients provided overall 2310 nights and **28173** hours of data	All 141 patients provided overall **9806** hours, with a median of 49.2 hours of data per patient. It is not clear how many of those hours recorded were of adults or children.	EQUIVALENT, No new concerns for performance or safety compared to the predicate device. Van Westrhenen et al. 2023 included significantly more hours of data than the study of the predicate device
Sensitivity Tonic-Clonic seizures Children	Overall 94% Mean 98% (95% CI: 94%- 100%)	Overall 96,9% Corrected Overall 91,5% (95% CI: 83%-95%)	EQUIVALENT, Both devices have a good sensitivity of >90% and equal false alarm rate. No new concerns for performance or safety compared to the predicate device.
Sensitivity Nocturnal epileptic major motor seizures	Overall 89% Mean 90% (95% CI: 84%-95%)	Not applicable	
False Alarm rate Children	Overall: 0,06/h Mean: 0,07/h (95% CI = 0.04–0.10/h)	Overall: 0,06/h (=1,35 per day/24h) Mean: 0,07/h= 1.63 per day/24h (95% CI: 0.04-0.10/h)= (95% CI: 1.06-2.28 per day/24h)	

Table 6: Summary of the study results of van Westrhenen et al 2023. and equivalence discussion to the predicate device study results.

2. S. Beniczky, & P. Ryvlin,. Standards for testing and clinical validation of seizure detection devices. Epilepsia, 59(S1), 9-13. 2018

Conclusion

The clinical study of van Westrhenen et al. 2023 demonstrates the ability of the NightWatch+ US to function as an assessment aid for monitoring of seizure activity in the intended population of children 4-16 years old and for the intended use setting.
Based on the above discussion and enclosed sections regarding substantial equivalence to the predicate device, we conclude that NightWatch+ US is substantially equivalent to its predicate device, Empatica Embrace [K181861] and does not raise any new or different questions of safety or effectiveness.