November 21, 2025

Neuro Event Labs Oy
Pierre Pelletier
Director of Regulatory Affairs and Quality Management
Biokatu 10
Tampere, 33520
Finland

Re: K251506
Trade/Device Name: Nelli (Version 7.11)
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: October 23, 2025
Received: October 23, 2025

Dear Pierre Pelletier:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251506

Please provide the device trade name(s).

Nelli (Version 7.11)

Please provide your Indications for Use below.

Nelli is indicated for use as an adjunct to seizure monitoring of patients aged 18 years and above in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. The system provides prioritization of identified major seizures and other motor events for review and media playback by a qualified healthcare professional.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Submitter Contact Details

Preparation Date:	2025-11-20
Applicant Name:	Neuro Event Labs Oy
Applicant Address:	Biokatu 10, 33520 Tampere, FINLAND
Applicant Contact Name:	Pierre Pelletier
Applicant Contact Telephone:	+358 50 303 5269
Applicant Contact Email:	pierre.pelletier@neuroeventlabs.com

Device Identification

Device Trade Name:	Nelli
Common Name:	Seizure monitoring system
Classification Name:	Non-electroencephalogram (EEG) physiological signal based seizure monitoring system
Regulation Number:	21 CFR §882.1580
Product Codes(s):	POS

Legally Marketed Device

Device Trade Name:	Embrace
Manufacturer:	Empatica S.R.L.
510(k) Number:	K181861

Device Description Summary

Nelli is a seizure detection and monitoring system based upon the analysis of audio/video recording which does not require the patient to be fitted with any body-worn accessory which may interfere with sleep and/or rest. Nelli uses machine learning algorithms to detect and categorize into review priority classes events indicative of seizure activity with a positive motor component. The identified events can be accessed and viewed in the interactive report as a scattergram through the web-based interface.

Indications for Use Statement

Nelli is indicated for use as an adjunct to seizure monitoring of patients aged 18 years and above in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. The system provides prioritization of identified major seizures and other motor events for review and media playback by a qualified healthcare professional.

Indications for Use Comparison

Identification of Subject Device and Predicate Device

Attribute	Subject Device	Predicate Device
Name	Nelli®	Embrace
Manufacturer	Neuro Event Labs Oy	Empatica S.R.L.
Reference	K251506	K181861
Indications for Use	Nelli is indicated for use as an adjunct to seizure monitoring of patients aged 18 years and above in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) to identify epileptic and non-epileptic seizure events with a positive motor component. The system provides prioritization of identified major seizures and other motor events for review and media playback by a qualified healthcare professional.	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.

Intended Use Comparison

Attribute	Subject Device	Predicate Device	Comparison
Type of Use	Prescription	Prescription	Same
Intended Use	Nelli is a non-EEG physiological signal-based seizure detection and quantification system.	Non-EEG physiological signal based seizure monitoring system.	Same
Target Condition	Convulsive seizures and non-convulsive motor seizures	Generalized tonic-clonic seizures	Similar - Safety & performance was clinically validated for the claimed seizure types. A benefit-risk assessment was conducted to demonstrate that the additional benefits of detecting non-convulsive motor seizures outweigh the additional risks, including the heightened false positive rate.
Use Environment	Healthcare facilities	Healthcare facilities and home	Similar - Safety & performance was clinically validated for the target use environment.
Population Age	18 years and above	6 years and above	Similar - Safety & performance was clinically validated for the claimed age groups.
Clinical Function	Adjunct to seizure monitoring	Adjunct to seizure monitoring	Same

Technological Comparison

Attribute	Subject Device	Predicate Device	Comparison
Recording Hardware	General purpose computer, microphone, camera, cables and mounting elements	Dedicated wearable biosensor	Similar - Interoperability of the recording hardware with the software was validated as part of the software testing.
Input Signals	Audio/video recording	Electrodermal activity sensor and accelerometer sensor	Similar - Safety & performance of the predicate device and of the subject device were clinically validated against video EEG.
Data Analysis	Machine learning enabled seizure detection algorithms	Machine learning enabled seizure detection algorithms	Same
Connectivity	The audio/video media is automatically uploaded to a cloud-based service, where it is processed by the device.	The sensor data is processed on the recording hardware, which is connected through Bluetooth to a mobile device with the dedicated application installed.	Similar - The connectivity of the recording hardware with the software was validated as part of the software testing.
Outputs	The identified events can be accessed on-line through the web-based user interface for annotation and classification by the clinician.	Detected seizures are communicated to the connected mobile device. The application initiates text messages or phone calls to caregivers through wireless network technology.	Similar - The functionality of the web interface including access to the identified events was validated as part of the software testing.
Bio-compatibility	Not applicable - No patient contacting component	Patient contacting part are tested for cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and skin irritation (ISO 10993-10).	Similar - No testing was required for Nelli.
MR Environment	Not evaluated	Not evaluated	Same
Sterility	Non-sterile	Non-sterile	Same
Electrical Safety, EMC, Mechanical Safety	Not applicable to the software components. The power supply of the recording equipment was tested for general safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2).	Hardware components were tested for general safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2).	Same

Nonclinical and Clinical Tests - Summary & Conclusions

Bench Testing

The bench tests performed to establish to validate Nelli for its intended purpose include the following:

- Software validation (documentation per guidance on device software functions[1])
- Training of detection algorithms using Artificial Intelligence (AI) (documentation per GMLP[2])
- Usability engineering (documentation per guidance on human factors[3])
- Cybersecurity (documentation per guidance on cybersecurity[4])
- Compatibility of recording hardware components in PRU configuration 2.1

The underlying processes from Neuro Event Labs' quality management system are based upon the requirements from the following FDA-recognized consensus standards:

- The risk management process complies with ISO 14971
- The symbols used in the labeling conform with ISO 15223-1 and ISO 7010
- The software life-cycle management process complies with IEC 62304
- The usability engineering process complies with IEC 62366-1
- The cybersecurity management plan is based upon IEC 81001-5-1 and AAMI TIR57

Animal Testing

No animal testing was performed.

Clinical Testing

As the special controls defined in 21 CFR §882.1580(b) require clinical performance testing for non-EEG physiological signal based seizure systems, a single-arm clinical investigation with performance goals has been conducted in three sites located within the United States in accordance with 21 CFR §812.2(b)(1) and ISO 14155, to demonstrate Nelli's ability to function as an assessment aid in the monitoring of seizure-related activity in the intended population and for the intended use setting.

The primary objectives include the event-level Sensitivity ("Se", expressed as Positive Percent Agreement) and False Detection Rate ("FDR", i.e. False Positives per hour) in convulsive seizures (tonic-clonic and bilateral clonic) when measured against an expert panel's review of video EEG (the current gold standard for seizure monitoring):

- Lower bound of the 95% confidence interval (CI) for Sensitivity > 70%
- Upper bound of the 95% confidence interval (CI) for False Detection Rate < 0.14 FP/hour

The secondary objectives include the event-level Sensitivity ("Se", expressed as Positive Percent Agreement) and False Detection Rate ("FDR", i.e. False Positives per hour) in other major motor seizures (tonic, unilateral clonic, or hyperkinetic seizures with a motor duration over 10s and other motor seizure types with a motor duration over 30s) when measured against an expert panel's review of video EEG (the current gold standard for seizure monitoring):

[1] Content of Premarket Submissions for Device Software Functions - June 2023
[2] Good Machine Learning Practice for Medical Device Development: Guiding Principles - October 2021
[3] Content of Human Factors Information in Medical Device Marketing Submissions - December 2022
[4] Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions - September 2023

- Lower bound of the 95% confidence interval (CI) for Sensitivity > 70%
- Upper bound of the 95% confidence interval (CI) for False Detection Rate < 8 FP/hour

The overall success criterion to conclude whether Nelli's performance characteristics are suitable for its intended purpose consists in the fulfillment of both primary objectives.

Subjects were recruited in 3 sites located in the United States as shown in Table 2. The data analysis combines two datasets from Phase I and Phase II. All subjects were 18 years or older.

Phase	Site	Number of Subjects	
		Intention-to-Monitor	Completed Cases*
I	TJU	104	100
II	TJU	44	43
	MLH	13	12
	USF	17	17
Total	All	178	172

The results met the specified performance goals for the primary and secondary objectives, as summarized in the tables below. No adverse event related to the use of Nelli was observed during the study.

Seizure Category	Subjects with Seizures [a]	Seizures (vEEG) [b]	True Positives	Sensitivity [c] (%)	Sensitivity [c] [95% CI]
I: High Priority (Convulsive)	26	58	49	84.5%	[74.6%, 94.2%]
II: Medium Priority (Other Major Motor)	40	121	102	84.3%	[75.2%, 91.9%]

Seizure Category	Total Subjects	False Positives	Total Hours	FDR [d] (FP/hour)	FDR [d] [95% CI]	FDR (FP/24 hours) [95% CI]
I: High Priority (Convulsive)	172	963	19244.0	0.050	[0.0376, 0.0636]	1.20 [0.902, 1.53]
II: Medium Priority (Other Major Motor)	172	116943	19244.0	6.08	[5.63, 6.54]	146 [135, 157]

a Number of subjects with events (as identified by vEEG) in the respective seizure category.
b Seizures identified by vEEG review during routine epilepsy monitoring unit admission.
c Event-level sensitivity calculated as (total TP / total TP + total FN)*100. 95% confidence intervals are estimated by using cluster bootstrapping method with resampling of subjects.
d Event-level FDR calculated as (total FP / total recording time). 95% confidence intervals are estimated by using cluster bootstrapping method with resampling of subjects.

Conclusions

The indications for use of the subject device are similar to the predicate device. The differences in claimed target conditions, use environment, and population age were clinically validated using the same methods as the predicate device demonstrating that the differences do not affect the safety and effectiveness of the subject device when used as labeled. The predicate device does not cover the type of nonconvulsive motor seizures in Category II, therefore a benefit-risk assessment was conducted to demonstrate that the additional benefits of detecting nonconvulsive seizures outweigh the increased risks, including the heightened false positive rate. The benefit-risk profile of Nelli with this additional feature remains favorable and comparable to the predicate device. Therefore, the differences in the indications for use do not constitute a new intended use.

The differences in recording hardware, input signals, connectivity, outputs, electrical safety, electromagnetic compatibility, and mechanical safety were validated by a combination of bench testing and clinical testing using the same methods as the predicate device. Biocompatibility was not relevant for the subject device. Therefore, the differences in technological characteristics do not raise different types of questions of safety and effectiveness.

The bench testing results established that Nelli is suitable to function as a seizure monitoring tool and to perform as intended in the specified use conditions. The clinical testing results demonstrated that Nelli achieves the specified performance goals for sensitivity and false detection rates, which were based upon the acceptance criteria for the predicate device and the other devices falling under product code POS and classification regulation 21 CFR §882.1580.

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as the predicate device.