June 11, 2026

Uneeg Medical A/S
Camilla Wismar
Senior Director, Regulatory & Quality
Borupvang 2
Alleroed, 3450
Denmark

Re: K253607
Trade/Device Name: UNEEG EpiSight System
Regulation Number: 21 CFR 882.1360
Regulation Name: Sub-scalp implanted electroencephalogram system for remote patient monitoring
Regulatory Class: Class II
Product Code: SEM
Dated: May 12, 2026
Received: May 12, 2026

Dear Camilla Wismar:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

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.	K253607

Please provide the device trade name(s).

UNEEG EpiSight System

Please provide your Indications for Use below.

The UNEEG EpiSight System is an electroencephalographic (EEG) recording and transmitting device system with a subcutaneous implant. It is indicated for continuous EEG recording in patients aged 18 and older with uncontrolled epilepsy.

The UNEEG EpiSight System is a prescription device intended to aid in physician's remote assessment and monitoring of the patient's condition. Remote assessment and monitoring are defined as the availability of EEG data for review by a healthcare provider located at a different location from where the data is being collected.

The medical use of the data acquired by the UNEEG EpiSight System is to be performed under the direction and interpretation of a licensed medical professional. The device does not provide diagnostic conclusions regarding the patient's condition.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
UNEEG EpiSight System, K253607

Contact Details (21 CFR 807.92(a)(1)

Applicant Name: UNEEG Medical A/S

Applicant Address: Borupvang 2
3450 Alleroed
Denmark

Applicant Contact Telephone: +45 4063 8000

Applicant Contact: Mrs. Camilla Wismar

Applicant Contact Email: cawi@uneeg.com

Device Name (21 CFR 807.92(a)(2)

Device Trade Name: UNEEG EpiSight System

Common Name: Sub-scalp implanted electroencephalogram system for remote patient monitoring

Classification Name: Sub-Scalp Implanted Electroencephalogram System For Remote Patient Monitoring

Regulation Number: 882.1360

Product Code(s): SEM

Legally Marketed Predicate Devices (21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
DEN240062	Minder System	SEM

Device Description Summary (21 CFR 807.92(a)(4)

The UNEEG EpiSight System is an electroencephalographic (EEG) recording and transmitting device system with a subcutaneous implant. The wearable recorder receives the transmitted EEG data from the implant. While the recorder is charging, EEG data will be automatically offloaded from the recorder through a Bluetooth Low Energy connection to the app installed on the patient's mobile phone. The patient's EEG is then transferred to the healthcare facility where it can be analyzed by the healthcare professionals using a 3rd party EEG review system.

The UNEEG EpiSight System provides objective, reliable, long term, and continuous EEG recordings allowing for a more complete understanding of a patient's condition and aiding a physician's clinical decision making regarding how best to treat the patient.

The UNEEG EpiSight System consists of an implantable device (UNEEG SubQ), a wearable recorder (UNEEG EpiSight Recorder), a dedicated app for the patient's smartphone (UNEEG EpiSight App) and cloud data transfer service (UNEEG Cloud and UNEEG ProConnect). The related accessories are a blunt needle (Introducing Needle), a baseplate (UNEEG EpiSight Baseplate) and a charger (UNEEG EpiSight Charger).

The implantable device measures the subcutaneous electroencephalogram (EEG) from two bipolar channels using a common reference. The implant consists of a housing that holds an electronic circuit and a lead with three electrodes which measure the EEG and the impedance. A specialized blunt needle is used for surgical insertion of the implant. The implant is placed subcutaneous pointing in the direction where the electrical activity is intended to be measured. The housing is placed behind the ear, and the lead can be placed in different positions.

The implant has a lifetime of 1 year after implantation. The safety of the implant beyond 1 year has not been established. Prior to expiration of this period the implant must be removed.

The wearable recorder supplies power to the implant and receives and stores the measured EEG. This is facilitated through a wireless inductive link whose function requires close transcutaneous alignment between the implant and the wearable recorder. The recorder enables communication and must be fixed to the skin behind the ear with a disposable baseplate. The baseplate situates the recorder onto the skin on top of the implant. The recorder can be dismounted from the baseplate without removing the baseplate from the skin if needed.

The recorder has a button for switching the recorder on/off and self-reporting of seizures, and a light indicator (LED) indicates functions during use. The recorder is wireless and rechargeable; charging is done by placing the recorder in the charger. While the recorder is charging, EEG data will be transferred from the recorder to the app installed on the patient's smartphone through a Bluetooth connection.

The app is the primary user interface in both setup and daily use of the UNEEG EpiSight System. The app guides proper alignment of the recorder when attaching recorder and baseplate on top of the implant. The app allows for self-reporting of seizures, and the patient can see average recording hours and total number of self-reported seizures. The app ensures that data from the recorder are uploaded to the healthcare facility when it is connected to the internet via either mobile data or Wi-Fi.

The recorded EEG data is transferred to UNEEG ProConnect at the healthcare facility through the UNEEG Cloud. Once transferred, the data will be decrypted and converted to a readable EDF+ format which can be analyzed by the healthcare professional using a 3rd party EEG review system.

Intended Use/Indication for Use (21 CFR 807.92(a)(5)

The UNEEG EpiSight System is an electroencephalographic (EEG) recording and transmitting device system with a subcutaneous implant. It is indicated for continuous EEG recording in patients aged 18 and older with uncontrolled epilepsy.

The UNEEG EpiSight System is a prescription device intended to aid in physician's remote assessment and monitoring of the patient's condition. Remote assessment and monitoring are defined as the availability of EEG data for review by a healthcare provider located at a different location from where the data is being collected.

The medical use of the data acquired by the UNEEG EpiSight System is to be performed under the direction and interpretation of a licensed medical professional. The device does not provide diagnostic conclusions regarding the patient's condition.

Indication for Use Comparison (21 CFR 807.92(a)(5)

The indication for use of the subject device, UNEEG EpiSight System, and the predicate device, Minder System, is highly similar. The differences do not affect safety and effectiveness of intended use.

Technological Comparison (21 CFR 807.92(a)(6)

The subject device, UNEEG EpiSight System, has very similar principles of operation and technological characteristics as the predicate device Minder System (DEN240062). The minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are the same between the subject and predicate device:

- Indication for use
- Battery type
- Wireless communication
- Electrode shape
- Sterilization method (implantable device)
- Features of wearable device user interface
- Cloud and data storage
- Features of patient app configuration and communication

The following technological differences exist between subject and predicate device:

- Implantation procedure / lead location
- Number of electrodes
- Electrode array length
- Method of wearing the external device
- MR Conditions
- Battery charging

The table below compares the principles of operation and operational/technological characteristics of the UNEEG EpiSight System and the predicate device.

	Subject Device	Primary Predicate Device	Equivalence Discussion
Device Name	UNEEG EpiSight System (UNEEG Medical A/S)	Minder System (Epiminder Pty. Ltd.) DEN240062	n/a
Regulation and Product Codes	21 CFR 882.1360 SEM	21 CFR 882.1360 SEM	Identical
Indications for Use	The UNEEG EpiSight System is an electroencephalographic (EEG) recording and transmitting device system with a subcutaneous implant. It is indicated for continuous EEG recording in patients aged 18 and older with uncontrolled epilepsy. The UNEEG EpiSight System is a prescription device intended to aid in physician's remote assessment and monitoring of the patient's condition. Remote assessment and monitoring are defined as the availability of EEG data for review by a healthcare provider located at a different location from where the data is being collected. The medical use of the data acquired by the UNEEG EpiSight System is to be performed under the direction and interpretation of a licensed medical professional. The device does not provide diagnostic conclusions regarding the patient's condition.	The Minder System is an electroencephalographic (EEG) recording and transmitting device implanted under the scalp. It is a prescription device indicated to acquire, transmit, and store EEGs continuously from patients between 18-75 years of age with drug-resistant epilepsy who are intolerant or not indicated for more conservative monitoring tools. The Minder System is intended to aid in a physician's remote assessment and monitoring of the indicated patient's condition. Remote patient assessment and monitoring for this use is defined as the patient's EEG data is available for review by a healthcare provider located at a different location from the patient and where the data is being collected. The medical use of the data acquired by the Minder System is to be performed under the direction and interpretation of a licensed medical professional. The Minder System does not provide any diagnostic conclusions about the patient's condition.	Highly similar. The differences in wording choice have the same meaning and do not affect safety and effectiveness of the device.
Implant Site	Subcutaneous, implant housing placed behind the ear with lead location adjustable based on seizure location.	Subgaleal space, placed ear to ear posterior to the vertex, with one pair of recording contacts over each hemisphere. The telemetry unit is secured in a postauricular bone well.	Different. Reduced risk of surgical complications due to less invasive implantation procedure. Implant body location is similar but lead location is different from

	Subject Device	Primary Predicate Device	Equivalence Discussion
			predicate. Differences allow for more targeted lead placement in the UNEEG EpiSight System allowing for placement closer to seizure initiation site. Additionally, the UNEEG SubQ implant does not require a skull recess to be created for placement of the lead and can be implanted under local anesthesia rather than general.
System Characteristics			
MR Conditions	MR Conditional (only implant)	Not publicly available	Non-clinical testing confirms the subject device conditional MR labeling.
Battery type	Rechargeable (external recorder)	Rechargeable (external wearable)	Identical
Wireless Communications	Implant to external recorder: inductive link Recorder to phone app: Bluetooth low energy	Implant to external wearable: inductive link Recorder to phone app: Bluetooth low energy	Identical
Implantable device			
Number of electrodes	3 (2 channels)	4 (2 bipolar pairs)	Different The differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Electrode shape	Cylindrical	Cylindrical	Identical
Individual Electrode surface area	1.10 mm diameter	0.6 mm diameter [cochlear]	Different The differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the

	Subject Device	Primary Predicate Device	Equivalence Discussion
			predicate including signal quality and ability to record relevant EEG patterns.
Electrode array length	103 mm long electrode lead	253 mm-long electrode lead	Different The differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Individual electrode length	10 mm	Not publicly available	Any differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Electrode spacing	20 mm	Not publicly available	Any differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Electrode material	Platinum/Iridium Alloy	Platinum [cochlear]	Different The differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG

	Subject Device	Primary Predicate Device	Equivalence Discussion
			patterns.
Lead body insulation material	ETFE (signal wire insulation)	Silicone elastomer [cochlear]	Different Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Implant housing material	Alumina Ceramic/Titanium	Titanium [cochlear]	Different Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Wire features	Multi-strand	Not publicly available	Any differences do not affect the safety and effectiveness of the subject device. Non-clinical and clinical testing confirms equivalent device performance to the predicate including signal quality and ability to record relevant EEG patterns.
Biocompatibility	Yes, ISO 10993-1	Yes	Identical
Sterilization method	Ethylene Oxide	Ethylene Oxide [cochlear]	Identical
External Device			
User interface	Integrated controls and visual indicators that allow the user to turn the device on/off, log seizures and monitor device status.	Integrated controls that allow the user to turn the device on/off and monitor device status.	Highly similar
Method of wearing the external device	The recorder is mounted in a baseplate containing an adhesive that can adhere to the skin. It is placed on the user's scalp behind the ear (aligning with the implant).	The Minder Wearable is placed over the ear and includes a wired connection to a receiver which magnetically connects to the implant.	Different. Non-clinical and clinical testing confirms equivalent device performance and safety to the predicate including signal quality

	Subject Device	Primary Predicate Device	Equivalence Discussion
			and ability to record relevant EEG patterns.
Size of external device	Length: 35 mm Width: 34 mm Thickness: 7 mm	Not publicly available	Any differences do not affect the safety and effectiveness of the subject device. Non-clinical testing confirms equivalent device performance and safety to the predicate.
Externally contacting materials	Adhesive on baseplate: Acrylate/polyethylene	Not publicly available	Any differences do not affect the safety and effectiveness of the subject device. Non-clinical testing confirms equivalent device performance and safety to the predicate.
Battery charging	Wireless charging, the recorder is fully charged within 8 hours.	Batteries are removed from the external device and charged through a wired connection. [Cochlear]	Different. Non-clinical testing confirms equivalent device performance and safety to the predicate.
Cloud and Data Storage			
Configuration	Software for data transferring and storage.	Software for data transferring and storage.	Identical
Purpose	Allow healthcare professionals to access patient data for viewing in a 3rd party system.	Allow healthcare professionals to access and download patient data for viewing.	Highly similar with identical functionality to review EEG data on a 3rd party EEG review system.
Communication	Secure internet connection.	Secure internet connection	Identical
Patient App			
Configuration	Software app installed on the patient's mobile phone that collects and transmits EEG data from the UNEEG EpiSight Recorder via Bluetooth and uploads it to UNEEG Cloud for secure transition storage before accessing in a hospital facility.	Software app installed on a mobile device collects and transmits EEG data from the Minder Wearable via Bluetooth and uploads it to Minder Cloud for secure storage and processing. It can also record entries for a patient's seizure diary.	Both systems allow for self-registration of seizures. Differences do not affect safety or effectiveness.
Communication	Blue tooth low energy	Blue tooth low energy	Identical

Benefit/Risk Summary

The subject device presents a different benefit-risk profile primarily due to its shorter labeled duration of use of up to 1 year compared to the predicate device that has up to 3 years duration of use. The shorter duration of implantation may reduce the cumulative benefit of long-term monitoring over time because continuous EEG data only is available in a shorter period. However, this potential reduction in duration-related benefit is balanced by a less invasive implantation procedure for the subject device. Specifically, the subject device does not require creation of a skull recess, bone removal, or tunneling, and it can be implanted under local anesthesia rather than general anesthesia. These differences reduce procedural burden and are expected to lower the risks associated with surgical implantation compared with the predicate device. In addition, the subject device allows targeted lead placement closer to the suspected seizure initiation site, while non-clinical and clinical testing support that the device provides clinically meaningful EEG recording performance and an acceptable safety profile for the duration of use period. Therefore, when used as intended for up to 1 year, the benefits of the subject device outweigh its risks and support substantial equivalence to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions (21 CFR 807.92(b)

Performance Bench Testing

The following bench testing was conducted to ensure appropriate safety and performance of the UNEEG EpiSight System.

Implant bench testing:

- Measurement and transmission of data and impedance
- Electrode Dielectric Strength
- Implant surface temperature
- Lifetime of use
- Recording performance per IEC 80601-2-26
- Flexural Stresses, Mechanical shocks and Tensile forces
- Immunity to diagnostic ultrasound
- Pressure changes and Vibration
- Hermetic seal

Wearable bench testing:

- Environmental conditions
- Free fall, vibration, shock
- Surface Temperature
- Battery Safety including charging protection

System bench testing:

- Data Transfer from the implant to the recorder
- Power of the implant through inductive link

Biocompatibility Testing

Biocompatibility testing was performed for the UNEEG EpiSight System in accordance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and FDA Guidance issued on September 8, 2023: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The implantable device, UNEEG SubQ, is categorized as an implant medical device with long-term (>30 days) direct contact with tissue. The risks associated with the implant device resulting in adverse tissue reaction or systemic toxicity effects have been evaluated through chemical characterization and subsequent toxicological risk assessment on the final finished device. The toxicological risk assessment concluded that the extractables from the test article, UNEEG SubQ, are unlikely to pose a toxicological safety concern.

Based on the toxicological risk assessment, the implant was evaluated for the following biocompatibility endpoints: cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), irritation/intracutaneous reactivity (ISO 10993-23), acute systemic toxicity (ISO 10993-11), material-mediated pyrogenicity (ISO 10993-11), subacute/subchronic systemic toxicity (ISO 10993-11), genotoxicity (ISO 10993-3), implantation (ISO 10993-6), chronic toxicity (ISO 10993-11) and carcinogenicity (ISO 10993-3). Evaluation of these biocompatibility endpoints were found to be adequate, with assessments supporting implantation for up to 1 year.

The Introducing needle is categorized as an external communicating medical device with limited (<24 hours) direct contact with tissue. The device was evaluated for the following biocompatibility endpoints: cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), irritation/intracutaneous reactivity (ISO 10993-23), acute systemic toxicity (ISO 10993-11), and material-mediated pyrogenicity (ISO 10993-11). Evaluation of these biocompatibility endpoints were found to be adequate.

The UNEEG EpiSight Recorder and UNEEG EpiSight Baseplate are categorized as surface medical devices with long-term (>30 days) direct contact with intact skin. The devices were evaluated for the following biocompatibility endpoints: cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), and irritation/intracutaneous reactivity (ISO 10993-23). Evaluation of these biocompatibility endpoints were found to be adequate.

Magnetic Resonance Imaging (MRI)

The implant is MR conditional. MRI scan can be performed safely on a person with the implant only under very specific conditions (1.5T and 3T). All external devices used in combination with the implant, such as the UNEEG EpiSight Recorder, are MR Unsafe.

Clinical Performance Data Summary (ULTRA)

Study Design:
The clinical study was a 12-week open-label, prospective study with a paired comparative design for pivotal evaluation of the safety and effectiveness of the 24/7 EEG SubQ in subjects with epilepsy involving the temporal lobe (NCT04526418). The study enrolled subjects in the United States at 5 sites and outside the United States (OUS) in Europe at 3 sites. The study included subjects with uncontrolled epilepsy and evidence supporting temporal lobe involvement. Subjects were implanted and followed during a 12-week period, for two sites up to a 52-week period of outpatient EEG recording, including a required Epilepsy Monitoring Unit (EMU) admission for concurrent video-EEG. Data was collected through device recordings, clinical examinations, seizure logs, and structured questionnaires.

Objectives:
Primary Objective – Effectiveness:

- Electrographic seizure recording sensitivity (TPF) of an ipsilaterally implanted device of at least 0.8: proportion of identified ipsilateral seizures as compared to ipsilateral video-EEG during admission to the Epilepsy Monitoring Unit
- False positive rate of at most 0.2: number of falsely identified ipsilateral seizures (false positives) per 24 hours as compared to ipsilateral video-EEG data.

Secondary Objectives – Safety:

- Nature and frequency of adverse events (AE) during the study and their severity, outcomes, and relationship to the device.

Secondary Objectives – Effectiveness:

- Median number of hours of subject device use per day during the study period of outpatient recording.
- Quality of EEG recorded by 24/7 EEG SubQ system as compared to video-EEG recordings in similar position during simulated home use and change in subcutaneous EEG quality at study completion.
- Change in electrode impedance over the study period of outpatient recording.

Enrollment results:
Subjects enrolled in the study were equally distributed between the sites in US and Europe. The study enrolled 64 subjects, 32 subjects in U.S. and 32 subjects OUS, 62 implanted, 9 discontinued, 60 completed the EMU, 55 completed 12 weeks follow up and 25 completed the 52 weeks follow up.

The study population reflects a clinically diverse epilepsy population, see Table 1, with a broad range of seizure burdens, ages of onset, and time spent alone during day and night, see Table 2.

Table 1: Baseline demographics of study population.

	Overall (N=64)
Sex	
Female	36 (56.3%)
Male	28 (43.8%)
Age (years)	
Mean (SD)	38.7 (13.2)
Median [Min, Max]	37.0 [18.0, 69.0]
BMI	
Mean (SD)	29.1 (7.03)
Median [Min, Max]	27.5 [19.2, 61.7]
Race	
White	46 (71.9%)
Black	5 (7.8%)
Asian or Pacific Islander & White	1 (1.6%)
Not applicable	1 (1.6%)
Missing	11 (17.2%)
Ethnicity (Hispanic/Latino or not)	
Hispanic/Latino	2 (3.1%)
Not Hispanic/Latino	51 (79.7%)
Not applicable	11 (17.2%)

Table 2: Subject Epilepsy History

	Overall (N=64)
Age at onset of epilepsy	
Mean (SD)	21.3 (15.0)
Median [Min, Max]	17.0 [0, 66.0]
Years since epilepsy onset	
Mean (SD)	17.0 (13.5)
Median [Min, Max]	14.0 [0, 51.0]

Results – Safety:

Safety analysis was performed on all 62 subjects implanted with the UNEEG SubQ device. A total of 84 AEs were reported throughout the study period. Most of the AEs and SAEs observed were reported to be unrelated to the device or study procedure, see Table 3. There was one serious, device-related adverse event (AEs) reported during this study caused by an infection at the implant site following the surgical procedure. Two other unrelated SAEs were reported. The remaining AEs were classified as mild (63 AEs) and moderate (18 AEs), and the most frequently reported event was “headache” (12 AEs), followed by “discomfort” (6 AEs), and “implant pain” (6 AEs).

Table 3: Summary of adverse events

Classification	Number of events (n = 84)	
	Relationship to device	Relationship to procedure
Not related	47	44
Unlikely	12	7
Possible	12	2
Probable	6	12
Causal relationship	7	19

Results – Effectiveness:

- Usage (adherence): The median total usage time for day and night was 13.9 hours and 8.6 hours, respectively, corresponding to adherence rates of daytime: 92.6% and nighttime: 95%. This is very high and supports clinically relevant usage patterns. No relevant difference was observed across age, sex, geography, race, or ethnicity.
- EEG quality assessment: The EEG recordings from the subcutaneous implant demonstrated non-inferiority compared with concurrent scalp EEG recordings across all predefined task groups simulating home use, based on a model-based analysis of pooled task-group scores and the protocol-defined non-inferiority margin (lower bound of the 95% CI > -0.5).
- Electrode impedance: The mean impedance across all subjects was 2.33 kΩ, and thus below the clinically recommended 5 kΩ. The population level impedance increase was -4.30 Ω/year with the upper bound of the 95% confidence interval for the slope being 59.27 Ω/year. This was below the predefined threshold of 540 Ω per year. This points to a robust electrical connection between the electrodes and the tissue throughout the study which is a proxy for good signal quality.
- Seizure detection: At the subject level, perfect ipsilateral seizure detection sensitivity (TPF = 1) was observed for more than half of the patients. The mean TPF was 0.785 (95% CI: 0.666–0.892), see Table 4. For the false positive rate (FPR), no false positive events were observed for all but two subjects. The observed mean FPR was 0.014 false positives per 24 hours (95% CI: 0.000–0.036). This indicates a low risk of false seizure detections.

Table 4: Bootstrap analysis of true positive fraction (TPF) and false positive rate (FPR).

	FAS Population (N=39)		
	Mean	95% CI[1]	P-value[1,2,3]
True Positive Fraction (TPF)	0.785	0.666, 0.892	0.593
False Positive Rate (FPR)	0.014	0.000, 0.036	<0.001

[1]Bootstrap 95% CI and p-value based of of sampling on subject with replacement 10,000 times.
[2]Null hypothesis that the TPF is less than or equal to 0.8.
[3]Null hypothesis that the FPR is greater than or equal to 0.2.

Additional Clinical Performance Data from other studies:

Findings from other clinical studies published in the literature support the safety and effectiveness of the UNEEG EpiSight System for the intended patient population. Key enrollment, performance, and safety outcomes from the published investigator-initiated studies are summarized in Table 5.

Table 5: Clinical evidence for investigator-initiated studies

	Study Title	**Subcutaneous EEG in epilepsy – proof of concept and clinical applications**	**Evaluation of sqEEG in subjects with uncontrolled epilepsy with genetic generalised epilepsy syndromes**	**Subcutaneous EEG: forecasting of epileptic seizures through investigation of long-term dynamics of seizure occurrences, stress, sleep and other factors.**
Study Information	No.	NCT02946151	NCT05241678	NCT04061707
	Country	Denmark	Ireland	United Kingdom
Enrollment				
Subjects (numbers)	Enrolled	10	9	15
	Completed	9	9	10
	Discontinued	1	0	5
Performance				
Exposure (days)	N	9	9	11
	Mean ± SD	99 ± 30	61 ± 40	380 ± 147
	Median (range)	98 (39-141)	54 (15-154)	433 (45-538)
Adherence rate (0-1)	N	9	9	11
	Mean ± SD	0.75 ± 0.15	0.74 ± 0.30	0.70 ± 0.28
	Median (range)	0.77 (0.45-0.91)	0.82 (0.07-0.98)	0.78 (0.17-0.99)
Safety		**N (events)**		
Adverse device events, classified by seriousness.	Serious	0	0	0
	Not serious	13	1	14
Device deficiencies	Count	0	0	15

Results – Safety

Across all studies used to support substantial equivalence, a total of two serious adverse device effects (SADEs), 130 adverse device effects (ADEs), and 243 device deficiencies (DDs) were reported, see Table 6. Among the 243 DDs, 108 were relevant to the subject device, the remaining 135 DDs were reported for previous prototype devices or software.

Table 6: Reported adverse device effects and device deficiencies (number of events) for the device system, including implant and recorder. Studies marked with * are ongoing, but data included here is peer-reviewed published.

Study	Study population	SADEs	ADEs					DDs (related/ unrelated)
			Headache	Implant site [a]	Infection[b]	Other[c]	Unclassified or unknown	
ULTRA	Epilepsy	1†	5	15	4	0	0	14 / 69
ULTS	Healthy	0	17	10	5	2	2	6 / 31
Baseplate	Healthy	0	0	0	0	22	0	53 / 0
P2H	Healthy	0	5	6	0	0	0	1 / 20
P2D	Type 1 diabetes	0	0	10	0	4	0	0 / 15
MTLE	Epilepsy	0	2	8	0	2	1	0
SUBER	Epilepsy	1	4	1	0	0	0	34 / 0
PREDYct*	Epilepsy	0	0	0	0	3	0	0
EMIRE*	Epilepsy	0	0	0	0	0	0	0
Epi-SubQ	Epilepsy	0	0	1	0	0	0	0
Filadelfia*	Epilepsy	0	0	0	1	0	0	0
Total	**-**	**2**	**33**	**51**	**10**	**33**	**3**	**108 / 135**

[a] Transient pain/soreness, discomfort, bruising, swelling, increased or decreased sensitivity near the implant, protrusion, replacement.
[b] Related to implant or surgical procedure.
[c] Skin irritation, itching at operation site, hypoglycemia.
† Infection at implant site following implantation.

Results – Effectiveness

- Usage (adherence): For the entire population with epilepsy, a total of 157 subjects, the median exposure time was 144 days with a mean ± SD = 216 ± 190 days. Across all epilepsy subjects with adherence information available (n=154), the observed median adherence was 73%, ≈17.5h per 24h, with a mean ± SD of 65±29%.
- EEG quality assessment: A clinical interpretability analysis for the ULTRA study demonstrated non-inferiority when comparing acceptable (score ≥ 3) versus unacceptable mean review scores for sqEEG and scalp-EEG. 33 of 34 paired assessments (97.1%) were classified as acceptable for both modalities, with one discordant pair. The paired difference in proportions (sqEEG minus scalp EEG) was −2.9% (95% CI −14.9% to 7.5%), meeting the predefined non inferiority margin of −15%. In the EpiSubQ study (N=8), Visual scoring (1–5) showed clear, interpretable EEG in 86% of scalp and 85% of sqEEG tasks, with comparable epileptiform morphology. In the P2H study (N=13), PSD comparison (−5 to 5 scale) showed sqEEG quality on par or better than scalp EEG, particularly during artifact-inducing tasks. Finally, in the P2D (N=8) and SUBER studies: assessments of predefined task demonstrated satisfactory EEG quality with clear physiological signals and artifacts across all subjects.
- Electrode impedance: In a meta-analysis of 3 different studies (P2D, MTLE and SUBER) the daily impedance check was analyzed for 27 subjects recording sqEEG for more than 1 year. Electrode impedances remained consistently low (<5 kΩ) across all subjects, with only a minor decreasing trend over time (-0.018 kΩ/month). These findings are further supported by the 3-months studies EpiSubQ (N=9) and P2D (N=8) where all measurements consistently remained low (<5 kOhm). No progressive changes in spectral characteristics or frequency-band power were observed in the reported studies, see Table 7, indicating stable signal quality over claimed implantation durations.

Table 7: Electrode impedance

Study	Subjects (N)	Mean electrode impedance (kΩ)	Change in impedance Ω/time period
ULTRA	60	2.33	4.30 per year (95% CI upper bound 59.27 per year)
UNEEG real-world dataset	5	<5	-21.49 per year (95% CI -28.35 to -14.62 /year)
Meta-analysis (P2H, MTLE and SUBER)	27	<5	-18 per month
EpiSubQ	9	<5	-
P2D	8	<5	-

Conclusion

Performance evaluation across the population demonstrated that the UNEEG EpiSight System enables continuous, ultra long-term EEG monitoring with signal quality comparable to scalp EEG, remaining stable over long-term use. It enables reliable, objective seizure monitoring across various seizure types and locations, often identifies more events than patient diaries, and supports clinical decision-making. Clinical data confirm the device is well-tolerated, unobtrusive, and does not interfere with daily activities.

Safety analysis showed an acceptable profile, with no unanticipated serious adverse device effects. Most adverse events were reported to be non-serious.

In conclusion, results of nonclinical and clinical tests have demonstrated that the UNEEG EpiSight System is safe, effective and performs equivalent to the predicate device for long-term EEG monitoring.