October 29, 2026

Epi-Minder Pty, Ltd.
Tracy Cameron
VP Clinical and Regulatory
Office 210/211 W. Podium, Mezzanine 2
525 Collins St.
Melbourne, Victoria 3000
Australia

Re: K262318
Trade/Device Name: Minder 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: September 30, 2026
Received: September 30, 2026

Dear Tracy Cameron:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JAIME RABEN -S

for Patrick Antkowiak, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K262318

Device Name
Minder System

Indications for Use *(Describe)*
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 12-75 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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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

510(k) Summary

Device Trade Name:	Minder System
Common Name:	Sub-scalp implanted electroencephalogram system for remote patient monitoring
Classification:	21 CFR 882.1360, Sub-Scalp Implanted Electroencephalogram System For Remote Patient Monitoring
Class:	II
Product Code(s):	SEM
Sponsor:	Epiminder Pty. Ltd. Office 210/211 West Podium, Mezzanine 2 525 Collins Street Melbourne VIC 3000 Australia
Contact:	Tracy Cameron VP Clinical and Regulatory Epi-Minder PTY LTD 384-388 Albert St Melbourne, Victoria 3002 Australia tcameron@epiminder.com 614-815-2323

Indications for use

The Minder System is indicated as follows:

> 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 12-75 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.

Device Description

The Minder System consists of implanted and externally worn components intended for continuously recording, transmitting, and storing EEG signals from patients between 12-75 years of age with drug-resistant epilepsy who are intolerant or not indicated for more conservative EEG monitoring tools. The

externally worn Minder Wearable receives the transmitted EEG signals from the Minder Implant and wirelessly transfers the signals to a Minder App stored on a mobile phone. The patient's EEG signals can then be downloaded from the mobile phone to a server for remote viewing and analysis by a physician.

Minder Implant:
The primary functions of the Minder Implant are:

- Receive and decode control commands from the Minder Wearable.
- Record EEG signals using two distinct channels (each channel supported by 2 electrodes).
- Transfer EEG signals through the skin to the Minder Wearable using inductive link.
- Measure, record, and transfer impedances and voltages measured on each electrode to the Minder Wearable.



Figure 1: Minder Implant with telemetry unit and electrode lead.

Minder Surgical Templates:
Minder Surgical Templates are provided by Epiminder to aid the physician with implantation of the Minder Implant.



Figure 2: Minder Surgical Templates.

Minder Wearable:
The Minder Wearable is positioned behind the ear and is always worn by the user during recording. Includes ear hooks and a clip to facilitate securing the Minder Wearable to the user. Some key functions of the Minder Wearable are the following:

- Control and command the Minder Implant to acquire physiological signals and voltages.
- Store and stream real-time EEG signals and other data from the Minder Implant to the Minder App via Bluetooth Low Energy (BLE).
- Provide status information to the Minder App:
    - Coil on/off status.
    - Battery level.
    - Faults.



Figure 3: Minder Wearable components.

Smartphone:
The smartphone is a commercially available Android phone. Epiminder supplies the phone and controls the phone through a Mobile Device Manager (MDM). The phone is locked down so only the Minder App is functional. The user does not have the ability to access any other phone features or install any other apps other than the Minder App. This controls the cybersecurity and performance of the smartphone when incorporated and used in the Minder System.

Minder App:
The primary functions of the Minder App are the following:

- Collect and locally store data from the Minder Wearable via an encrypted BLE.
- Conduct Minder Implant integrity checks via electrode impedance measurements.
- Upload data to the cloud for secure storage and access.
- Record and upload patient-reported events.

Minder Cloud:
Minder Cloud is a web-based application that provides physicians secure access to patient data. The data from the cloud storage may be exported by the physician to a local computer or network drive to be viewed and analyzed using Epiminder specified EEG review software that is legally marketed for this purpose in the United States (U.S.).

The primary functions of the Minder Cloud are as follows:

- Patient administration.
- Clinic (site) and clinician registration.

- EEG and patient-reported event data export functions.
- Authentication and authorization functions for Minder App and the web-based portal, and access to data stored in Minder Cloud.
- Authenticated endpoints for Minder App to upload collected EEG data and patient reported events.
- Ingestion, processing, storage, and export of EEG data.
- Security, privacy, logging, and auditing functionality.

Predicate Device
The Epiminder Minder System (subject device) is substantially equivalent to the primary predicate (Epiminder Minder System – DEN240062) previously cleared with respect to indications, design, function, and materials, as outlined below.

Technological Comparison
The subject device, Epiminder Minder System, has identical principles of operation and technological characteristics to the predicate device Minder System (DEN240062). There have been no changes to hardware or software since DEN240062 was granted resulting in no changes to the device safety and effectiveness.

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

Non-Clinical and Clinical Tests Summary & Conclusions

Performance Bench Testing
The subject device, Epiminder Minder System, has identical hardware and software to the predicate device Minder System (DEN240062). There have been no changes to the device since DEN240062 was granted resulting in no changes to the device safety and effectiveness. All previously reviewed bench testing was leveraged from DEN240062 to ensure appropriate safety and performance of the Minder System.

Clinical Performance Data Summary – Pediatric Extrapolation
The current submission provides justification to extrapolate the existing clinical data reviewed during DEN240062 to the 12 - 17 adolescent pediatric patient population. This justification provides anatomical, biomechanical, and device-specific information that supports substantial equivalence between the Minder System indicated for use in 12 – 75 year old patients (subject device) and the Minder System indicated for use in 18 – 75 year old patients (predicate device).

Per the FDA guidance document titled "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices" dated June 21, 2016, the following conclusions were utilized to leverage previously collected data (18-75) to extrapolate to the current intended population (12 – 17):

A. Drug-resistant epilepsy (DRE) of various types (e.g., focal, generalized) are observed in adolescent pediatric patients from 12 to 17 years of age.
B. The primary and secondary endpoints of the clinical validation study described in DEN240062 address the same safety and effectiveness questions relevant to Minder System use in adolescent pediatric patients from 12 to 17 years of age. The ability of the device to accurately record EEG activity is expected to be highly important in this population.
C. The location and duration of implantation between the FDA-authorized population (18 – 75

years of age) and the adolescent pediatric patients from 12 to 17 years do not differ in any way that would impact safety or effectiveness of the Minder System.

D. There are no changes to the Minder System with respect to the fundamental technological characteristics that are important to achieving clinical function, and the system does not need to be modified for the pediatric sub-population.
E. The stage of anatomical development reached by the intended pediatric subpopulation suggests a cranial and brain size that is substantially equivalent to that of the FDA-authorized patient population.
F. There are no differences in the characteristics of EEG recordings or the nature of epileptiform activity that could degrade the safety or effectiveness of the Minder System when used in adolescent pediatric patients from 12 to 17 years of age.

A risk analysis update was conducted in accordance with ISO 14971 to evaluate potential risks related to growth between 12 and 17 years of age. The conclusion is that no design modifications for the Minder System are required to ensure the device is as safe and as effective when used in the entire subpopulation of adolescent pediatric patients.

	Primary Predicate Minder System DEN240062	**Subject Device** Minder System	**Comparison**
Manufacturer	Epiminder Pty. Ltd.	Epiminder Pty. Ltd.	Same
Device Name	Minder System	Minder System	Same
Regulation Number	882.1360	882.1360	Same
Product Code	SEM	SEM	Same
OTC / Rx	Rx	Rx	Same
Intended Use / Indications for Use	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.	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 12-75 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.	Similar. The current submission includes a change to the indications for use to update the intended age range for patients. Any new concerns related to safety and effectiveness are addressed through a pediatric extrapolation.
Implant Site	Subgaleal space, placed behind the with leads placed across the back of the skull.	Subgaleal space, placed behind the with leads placed across the back of the skull.	Same
Battery	Rechargeable	Rechargeable	Same
Wireless Communications	Inductive link used to power and transmit data from the implant. Bluetooth used to transfer data from recorder to phone app	Inductive link used to power and transmit data from the implant. Bluetooth used to transfer data from recorder to phone app	Same
Number of	4	4	Same

	Primary Predicate Minder System DEN240062	**Subject Device** Minder System	**Comparison**
electrodes			
Electrode array length	253 mm	253 mm	Same
Electrode material	Platinum	Platinum	Same
Lead body insulation material	Silicone elastomer	Silicone elastomer	Same
Receiver material	Titanium	Titanium	Same
Biocompatibility	ISO 10993-1 compliant	ISO 10993-1 compliant	Same
Sterilization method	Ethylene Oxide	Ethylene Oxide	Same
External device	The Minder Wearable is positioned behind the ear and is always worn by the user during recording. Includes ear hooks and a clip to facilitate securing the Minder Wearable to the user.	The Minder Wearable is positioned behind the ear and is always worn by the user during recording. Includes ear hooks and a clip to facilitate securing the Minder Wearable to the user.	Same
Software	Cloud data storage and transfer to allow healthcare professionals to access and download patient data for viewing. Patient app primary functions are to 1) collect and locally store data from the Minder Wearable via an encrypted BLE; 2) Conduct Minder Implant integrity checks via electrode impedance measurements; 3) Upload data to the cloud for secure storage and access; 4) Record and upload patient-reported events.	Cloud data storage and transfer to allow healthcare professionals to access and download patient data for viewing. Patient app primary functions are to 1) collect and locally store data from the Minder Wearable via an encrypted BLE; 2) Conduct Minder Implant integrity checks via electrode impedance measurements; 3) Upload data to the cloud for secure storage and access; 4) Record and upload patient-reported events.	Same

Conclusion

The Minder System device hardware and software have not changed since the approval of DEN240062. All non-clinical testing from DEN240062 was leveraged to support the current device submission.

Clinical Performance evaluation reviewed under DEN240062 was utilized to support pediatric extrapolation of the patient population from ages 18 – 75 to also include ages 12 – 17. The Minder System enables reliable, objective EEG monitoring across various cranial locations to support clinical decision-making. Clinical data confirm the device is well-tolerated, unobtrusive, and does not interfere with daily activities.

The subject device, which now includes pediatric patients aged 12 - 17, has the same intended use as the predicate device. The differences between the subject and predicate patient populations do not raise different questions of safety and effectiveness with respect to indications for use, design, materials, function, and performance. Therefore, the subject device Minder System has been found to be substantially equivalent to the predicate device (Minder System, DEN240062).