August 19, 2026

Pascall Systems, Inc.
% Robert Steurer
Consultant
Steurer Consulting Group
800 Blue Quail Rd.
Keller, Texas 76248

Re: K254213
Trade/Device Name: Pascall Sensor Unit (PSU1)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, GXY, OMC, ORT
Dated: July 20, 2026
Received: July 20, 2026

Dear Robert Steurer:

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

Patrick Antkowiak
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.*

510(k) Number *(if known)*
K254213

Device Name

Wireless EEG System

Indications for Use *(Describe)*

The Pascall Systems, Inc. Wireless EEG System is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the forehead and wirelessly transmitting the electroencephalographic (EEG) signals for storage and display. The Pascall Systems, Inc. Wireless EEG System is intended for use in the acquisition of EEG signals, displaying them in real time and storing them for later review and analysis. The Pascall Systems, Inc. Wireless EEG System is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as a physician's office, laboratory, clinic, or in outpatient settings.

The Pascall Systems, Inc. Wireless EEG System is indicated for use on patients 18 years of age or older and is to be used under the direction and interpretation of a licensed medical professional. The Pascall Systems, Inc. Wireless EEG System does not provide any diagnostic conclusion 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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**510(k) Summary**

| | |
|---|---|
| Date Prepared: | June 9, 2026 |
| Submitter: | Pascall Systems Inc.<br>625 Massachusetts Ave<br>Cambridge, MA 02139 |
| Submitter Contact: | Pascall Systems Inc.<br>625 Massachusetts Ave<br>Cambridge, MA 02139<br><br>Tuan Le Mau<br>Pascall Systems, Inc.<br>Phone: +1 (617) 251 7442<br>email: tuan@pascallsystems.com |
| Application Correspondent: | Robert Steurer<br>Principal Consultant<br>Steurer Consulting Group<br>800 Blue Quail Rd.<br>Keller, TX 76248<br>steurerbob@gmail.com<br>+1 (425) 358-1072 |
| Manufacturing Site: | Pascall Systems Inc.<br>625 Massachusetts Ave<br>Cambridge, MA 02139 |
| Trade/Proprietary Name: | Pascall Wireless EEG System |
| Common/Usual Name: | Pascall Wireless EEG System |
| Device Class: | Class II |
| Primary Classification Reg.: | 882.1400 |
| Primary Product Code: | OLT |
| Additional Product Code: | OMC, ORT, GXY |
| Predicate Device: | Pascall Wireless EEG System (K213299) |
| Secondary Predicate Device: | Covidien/BIS EEG VISTA Monitor System (K072286) |

| | |
|---|---|
| Device Description: | The Pascall Wireless EEG System with PSU1 is a non-invasive EEG monitoring system that records and displays EEG signals acquired from electrodes placed on the patient's forehead. The system consists of:<br>• PSU1 Sensor Unit – a single-use, integrated disposable patch and sensor containing medical-grade adhesive, three Ag/AgCl electrodes, two CR2016 coin-cell batteries, a BLE wireless module, and a multicolor LED indicator.<br>• Clinician Display Module (CM0D) – a 10.1-inch tablet that displays real-time EEG and spectrograms and stores data for retrospective review.<br>The PSU1 replaces the previous two-piece M0P/M0S configuration by combining the patch and sensor into a single disposable unit. |
| Intended Use: | The Pascall Systems, Inc. Wireless EEG System is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the forehead and wirelessly transmitting the electroencephalographic (EEG) signals for storage and display. The Pascall Systems, Inc. Wireless EEG System is intended for use in the acquisition of EEG signals, displaying them in real time and storing them for later review and analysis. The Pascall Systems, Inc. Wireless EEG System is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as a physician's office, laboratory, clinic, or in outpatient settings.<br><br>The Pascall Systems, Inc. Wireless EEG System is indicated for use on patients 18 years of age or older and is to be used under the direction and interpretation of a licensed medical professional. The Pascall Systems, Inc. Wireless EEG System does not provide any diagnostic conclusion about the patient's condition. |
| Summary of Technological Characteristics: | The PSU1 maintains the same fundamental technology as the predicate device, including:<br>• EEG acquisition principles<br>• Signal processing and display architecture<br>• Bluetooth Low Energy wireless communication<br>• Intended use and clinical workflow |

However, several design and material modifications were made relative to the predicate. These include:

- Change in adhesive material (3M 1773 → MED 5741)
- Removal of foam spacer layer
- Change in enclosure materials (Spectramelt → PolyJet multi-material)
- Change in power source (ER2450T → dual CR2016)
- Addition of battery pull-tab
- Reduced PCB footprint
- Reduction from 4 EEG channels to 2 EEG channels

These modifications do not alter the device's intended use or essential performance.

Technology Comparison: The Pascall Systems Inc. Wireless EEG System employs the same technological characteristics as the predicate device and the reference predicate device.

| Characteristic | Primary Predicate Device (M0P/M0S, K213299) | Secondary Predicate Device (BIS EEG VISTA Monitor System, K072286) | Subject Device (PSU1) | Notes / Rationale |
|---|---|---|---|---|
| **Intended Use / Indications** | The Pascall Systems, Inc. Wireless EEG System is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the forehead and wirelessly transmitting the electroencephalographic (EEG) signals for storage and display. The Pascall Systems, Inc. Wireless EEG System is intended for use in the acquisition | The BISx is intended for use W1der the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. The BISx, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor | The Pascall Systems, Inc. Wireless EEG System is intended to be used for measuring and recording the electrical activity of a patient's brain, obtained by placing electrodes on the forehead and wirelessly transmitting the electroencephalographic (EEG) | No change in intended use from primary predicate device. |

| Characteristic | Primary Predicate Device (M0P/M0S, K213299) | Secondary Predicate Device (BIS EEG VISTA Monitor System, K072286) | Subject Device (PSU1) | Notes / Rationale |
|---|---|---|---|---|
| | of EEG signals, displaying them in real time and storing them for later review and analysis. The Pascall Systems, Inc. Wireless EEG System is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as a physician's office, laboratory, clinic, or in outpatient settings. The Pascall Systems, Inc. Wireless EEG System is indicated for use on patients 18 years of age or older and is to be used under the direction and interpretation of a licensed medical professional. The Pascall Systems, Inc. Wireless EEG System does not provide any diagnostic conclusion about the patient's condition. | the state of the brain by data acquisition of EEG signals.<br>The BIS Index, one of the BlSx output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recov□ time.<br>Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation. | signals for storage and display. The Pascall Systems, Inc. Wireless EEG System is intended for use in the acquisition of EEG signals, displaying them in real time and storing them for later review and analysis. The Pascall Systems, Inc. Wireless EEG System is intended for use in a hospital Operating Room, Post Anesthesia Care Unit, Intensive Care Unit, Emergency Department, or in other medical facilities such as a physician's office, laboratory, clinic, or in outpatient settings.<br>The Pascall Systems, Inc. Wireless EEG System is indicated for | |

| Characteristic | Primary Predicate Device (M0P/M0S, K213299) | Secondary Predicate Device (BIS EEG VISTA Monitor System, K072286) | Subject Device (PSU1) | Notes / Rationale |
|---|---|---|---|---|
| | | | use on patients 18 years of age or older and is to be used under the direction and interpretation of a licensed medical professional. The Pascall Systems, Inc. Wireless EEG System does not provide any diagnostic conclusion about the patient's condition. | |
| **Overall System Architecture** | Two-piece system: disposable patch (M0P) + reusable sensor (M0S) | Two-piece system: disposable electrodes connects to reusable module | Single integrated disposable patch + sensor | Simplifies workflow; no change to fundamental technology. |
| **EEG Channels** | 4 channels | 2 or 4 channels depending on monitor used | 2 channels | Bench testing shows equivalent performance for intended use. |
| **Electrode Count** | 6 electrodes (2 reference, 4 active) | Depends on sensor used – BIS bilateral sensor = 6 electrodes, Quatro sensor = 4 electrodes | 3 electrodes (1 reference, 2 active) | Reduced montage; validated through performance testing. |
| **Electrode Type** | Hydrogel | Potassium chloride (KCl) aqueous gel | Hydrogel | Same material type as |

| Characteristic | Primary Predicate Device (M0P/M0S, K213299) | Secondary Predicate Device (BIS EEG VISTA Monitor System, K072286) | Subject Device (PSU1) | Notes / Rationale |
|---|---|---|---|---|
| | | | | primary predicate. |
| **Patch Adhesive** | 3M 1773 polyolefin foam with acrylic adhesive | Not Available | MED 5741 polyester nonwoven with acrylic adhesive | MED 5741 is thinner, breathable, and optimized for flexible wear. |
| **Patch Stack-Up** | Includes foam spacer layer (non-contact) | Not Available | Spacer layer removed | Reduces profile. |
| **Enclosure Material** | Spectramelt 220 (low-pressure overmold) | Not Available | PolyJet 3-material print (Vero Black, Vero Clear, 60A durometer overmold) | Supports low-volume manufacturing; no change to performance. |
| **Power Source** | 1× ER2450T 3.6V lithium cell | Power in connected module | 2× CR2016 3V coin cells in series | Lower power consumption enables smaller battery format. |
| **Activation Method** | No pull-tab | Power in module when connected to monitor | Battery pull-tab added | Standard for single-use electronics; no effect on wireless function. |
| **PCB Layout** | Larger footprint | Not Applicable | Reduced footprint | Supports smaller enclosure. |
| **Wireless Technology** | BLE primary; NFC secondary pairing method | Wired, no wireless | BLE only | NFC removed; BLE validated as reliable; reduces attack surface. |

| Characteristic | Primary Predicate Device (M0P/M0S, K213299) | Secondary Predicate Device (BIS EEG VISTA Monitor System, K072286) | Subject Device (PSU1) | Notes / Rationale |
|---|---|---|---|---|
| **Signal Transmission** | Bluetooth Low Energy | Wired, no wireless | Bluetooth Low Energy | Same wireless protocol. |
| **Signal Processing** | Performed in CM0D tablet | Performed in module and monitor | Same | No change. |
| **Display Module** | 10.1-inch CM0D tablet | Depends on monitor used | Same | No change. |
| **Shelf Life** | Patch: 6 months; Sensor: 2 years | Not Available | PSU1: 6 months | Consistent with disposable design. |
| **Reusability** | Patch disposable; sensor reusable | Electrode disposable, module reusable | Fully disposable | Reduced risk from primary predicate, no reprocessing required. |
| **Biocompatibility** | ISO 10993 cytotoxicity, sensitization, irritation | ISO 10993 cytotoxicity, sensitization, irritation | Same testing performed; cytotoxicity | No Change |
| **Performance Standards** | IEC 60601-1, 60601-1-2, ISO 80601-2-26 | Not Available | Same | All essential performance requirements met. |

## Performance Testing Summary

### Non-Clinical Bench Performance Testing Information

#### Performance Testing

Bench testing was performed in accordance with:

- IEC 60601-1
- IEC 60601-1-2
- ISO 80601-2-26

Testing demonstrated compliance with:

- Measurement accuracy
- Input dynamic range
- Noise
- Frequency response
- Common-mode rejection

All results met specifications.

#### Biocompatibility

All patient-contacting materials were evaluated per ISO 10993 for:

- Cytotoxicity
- Sensitization
- Irritation

#### Wireless Technology and Cybersecurity

The predicate device included NFC as a secondary pairing mechanism. The subject device removes NFC and uses BLE exclusively. BLE was already the primary wireless method in the predicate. Removal of NFC:

- Does not affect intended use
- Does not affect performance
- Reduces the wireless attack surface
- Maintains Cybersecurity per FDA Guidance Documents

***Sterilization and Shelf Life:*** The Pascall Systems, Inc. Wireless EEG System is not provided sterile. The Pascall Systems, Inc. Wireless EEG System components have a shelf life as follows:

a) M0 Patch (M0P) is the component that contains the electrodes, battery, and adhesive to attach to the patient skin and has a storage shelf life of 6 months

b) M0 Sensor (M0S) is the sensor component that contains the electronics and has a shelf life of 2 years

c) PSU1 Patch/Sensor has a storage shelf life of 6 months

d) Clinician M0 display (CM0D) has no stated shelf life

## Discussion

Based on the comparison of technological characteristics, performance testing, biocompatibility evaluation, and unchanged intended use, the Pascall Wireless EEG System with PSU1 is substantially equivalent to the predicate device (K213299).