March 30, 2025

Precision Neuroscience, Corp.
Jayme Strauss
Chief Clinical and Commercial Officer
5201 Great America Pkwy, Suite 432
Santa Clara, California 95054

Re: K242618
Trade/Device Name: Layer 7-T
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: February 27, 2025
Received: February 27, 2025

Dear Jayme Strauss:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K242618

Device Name
Layer 7-T

Indications for Use *(Describe)*
Layer 7-T cortical electrodes are intended for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The electrodes may be placed in either open or burr hole procedures with the optional use of standard imaging techniques such as intraoperative x-ray, fluoroscopy, and computerized tomography (CT).

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Precision Neuroscience, Corp.'s Layer 7-T

K242618

Submitter:

5201 Great America Pkwy
Suite 432
Santa Clara, CA 95054
United States

Phone: (646) 771-5881

Contact Person: Jayme Strauss

Email Address: Jayme.Strauss@precisionneuro.io

Date Prepared: February 18, 2025

Name of Device: Layer 7-T

Common or Usual Name: Cortical electrode

Classification Name: Electrode, Cortical

Regulatory Class: 21 CFR 882.1310

Product Code: GYC

Predicate Device: K191186

Ad-Tech Medical Instrument Corporation

- Subdural Strip/Intraoperative Strip Electrode
- Subdural Grid/Intraoperative Grid Electrode
- Dual-Sided Interhemispheric Subdural Electrode
- Multi-Strip and Split Grid Subdural Electrode
- Intraoperative Mapping Grid Subdural Electrode

Device Description:

The Layer 7-T is intended for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The electrodes may be placed in either open or burr hole procedures with the optional use of standard imaging techniques such as intraoperative x-ray, fluoroscopy, and computerized tomography (CT).

The overall Layer 7-T consists of a sterile thin film 1024-electrode array connected to a more rigid PCB package (known as the headstage) with ribbon cables. Each ribbon cable connects to 64 channels from the electrode array. There are a total of 16 ribbon cables in the headstage, connecting 1024 electrodes on the array. The device is also provided with an intermediary yoke cable that connects the ribbon cables from the Layer 7-T headstage to standard EEG equipment via 64 standard DIN connectors. A yoke stand is also provided as an optional accessory that allows up to 16 yokes to be stacked. Surgical accessories are provided with the array and are intended to aid in deployment of the array.

The system allows the surgeon to place electrode arrays on the surface of the brain through burr holes. The inserted portion of the device can be retrieved following use by pulling the electrode array through the burr hole.

The thin film electrode array is designed to operate in a fashion identical to the currently used ECoG arrays, in that it is to be placed on the surface of the brain to interface with brain tissue through electrical recording and stimulation.

The electrode array consists of a polyimide substrate with platinum electrodes and associated electrically connecting traces and another layer of polyimide on top. A polyimide pocket is adhered via silicone to the backside of the electrode array tip. The array also contains gold radiopaque markers embedded in the silicone pocket adhesive. A rigid stainless steel radiopaque stylet is temporarily placed in the pocket during electrode array deployment.

The overall Layer 7-T system, including the yoke, is intended for single use only. The Layer 7-T is a passive device and only receives power from a connected FDA-cleared EEG system. It does not have any wireless capabilities and does not contain any software. It is not MRI-compatible. It is only intended for use in a professional healthcare environment.

Intended Use / Indications for Use

Intended Use/Indications for Use:

Layer 7-T cortical electrodes are intended for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The electrodes may be placed in either open or burr hole procedures with the optional use of standard imaging techniques such as intraoperative x-ray, fluoroscopy, and computerized tomography (CT).

Indications for Use Comparison to Predicate:

The proposed intended use for the Layer 7-T and the intended use for the Ad-Tech Subdural Electrodes (K191186) are identical. Both devices intended for temporarily placement on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

There are minor differences in the indications for use for the Layer 7-T and the indications for use of the Ad-Tech Subdural Electrodes. Both devices are indicated for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The Layer 7-T indications state that the device may be placed in either open or burr hole procedures with the optional use of fluoroscopic imaging. This

additional language in the indications for use for the Layer 7-T does not alter the intended effect of the device or create a new intended use. These differences in indications are representative of the difference in technological characteristics are supported by performance testing which demonstrates that the Layer 7-T electrodes are as safe and effective as the predicate.

Summary of Technological Characteristics:

Both the Layer 7-T and the Ad-Tech Subdural Electrodes are sterile, single-use electrical conductors that are temporarily placed on the surface of the brain. Both of these devices record and/or monitor the brain's electrical activity as well as stimulate the brain. Both devices also operate in a similar manner, which is by using provided cables to connect the device to an external commercially available EEG or cortical stimulation system for recording, monitoring or stimulating.

The Layer 7-T has several minor differences as compared to the predicate including: higher electrode count, smaller contact diameter and smaller electrode body surface area. The Layer 7-T electrode array is made of polyimide and the electrode contact material is made of platinum while the Ad-Tech Subdural Electrodes are made of silicone with a platinum/iridium electrode contact material. Unlike the predicate, the Layer 7-T electrode array is also designed with an integrated pocket on the underside of the array and is provided with its own surgical tools to aid in deployment. Lastly, the Layer 7-T incorporates a printed circuit board (PCB) bonded to the electrode array. The PCB does not raise any new safety or effectiveness questions compared to the predicate, as the PCB-electrode interface is outside the body and fully enclosed in biocompatible packaging material. The PCB board has no active electronic components, and functions solely as a conduit that directs signals from the brain to connectors during recording and use. These differences do not raise new questions of safety or effectiveness and are supported by bench and animal performance data which demonstrate that the Layer 7-T is as safe and effective as the Ad-Tech Subdural Electrodes

A table comparing the key features of the subject and predicate devices is provided below.

Feature	Layer 7-T (Subject Device)	Ad-Tech Subdural Electrodes (K191186)	Comment
Indications for Use	Layer 7-T cortical electrodes are intended for temporary (less than 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The electrodes may be placed in either open or burr hole procedures with the optional use of standard imaging techniques such as intraoperative x-ray, fluoroscopy, and computerized tomography (CT).	The Ad-Tech Subdural Electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Dual-Sided Interhemispheric, MultiStrip and Split Grid, Intraoperative Mapping Grid) are intended for temporary (< 30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals on the surface of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	The Layer 7-T includes additional language on the surgical procedure and the use of optional imaging during placement of the array. This does not alter the intended effect of the device or create a new intended use.

Feature	Layer 7-T (Subject Device)	Ad-Tech Subdural Electrodes (K191186)	Comment
Clinical Application	Placed on the surface of the brain to support recording, monitoring, and stimulation.	Placed on the surface of the brain to support recording, monitoring, and stimulation.	Same
Contraindications	The Layer 7-T electrode array should not be used on any patient whom the physician/surgeon considers at risk for infection. The Layer 7-T electrode array is not intended for continuous stimulation. Stimulation should only be applied to support the brain mapping purpose of the array.	The subdural electrodes should not be used on any patient whom the physician/surgeon considers at risk for infection. The subdural electrodes are not intended for continuous stimulation. Stimulation should only be applied to support the brain mapping purpose of the electrodes.	Same
Single patient use, Disposable	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same
Provided Non-Sterile (to be sterilized by the user)	No	No	Same. Electrodes are provided sterile. The yokes and yoke stand are additional device accessories for the Layer 7-T and are provided non-sterile. They do not contact the patient.
Environment of Use	Operating Rooms and Temporary monitoring	Operating Rooms and Temporary monitoring	Same
Duration of Use	<30 days	<30 days	Same
Electrode Body Surface Area	4.02cm^2	$\leqslant 138 cm^2$	The smaller surface area does not impact safety or effectiveness. Biocompatibility testing along with GLP animal testing demonstrate safety of the device. Bench testing over a comparable area also demonstrates that the functionality is the same.

Feature	Layer 7-T (Subject Device)	Ad-Tech Subdural Electrodes (K191186)	Comment
Electrode Contact Material	Platinum	Platinum/Iridium or Stainless Steel	This difference does not raise new questions of safety and effectiveness and the device performance data support the electrical stimulation is as safe and effective as the predicate.
Maximum Stimulation Charge Density	$\leqslant 50\mu C/cm^2$	$\leq 30\mu C/cm^2$	Shannon Criteria ($k < 1.75$) is more than satisfied for the Layer 7-T array. Microelectrodes and electrodes in this size range (~0.1 mm^2 scale) have been shown to allow higher charge density limits as they go away from Shannon conditions. However, the Layer 7-T still stimulates at lower intensities to ensure safety across all parameters.
Number of contacts per electrode	1024	Strips: 1-16 Grids: 3-128	Larger numbers of electrodes alone do not impact device safety, as demonstrated by biocompatibility testing, GLP animal testing, and electrical safety testing. Functionality is verified by bench testing and demonstrated to be equivalent to the predicate.

Feature	Layer 7-T (Subject Device)	Ad-Tech Subdural Electrodes (K191186)	Comment
Stimulation Frequency	Not to exceed 50Hz	Not indicated in labeling	While the predicate does not specify these values in their labeling, the addition of these values to our labeling does not raise new questions of safety and effectiveness, and is supported by performance testing.
Stimulation Pulse Trains	Not to exceed 15 seconds	Not indicated in labeling	While the predicate does not specify these values in their labeling, the addition of these values to our labeling does not raise new questions of safety and effectiveness, and is supported by our performance testing.
Pulse train duty cycle	Not to exceed 50%	Not indicated in labeling	While the predicate does not specify these values in their labeling, the addition of these values to our labeling does not raise new questions of safety and effectiveness, and is supported by our performance testing.

Feature	Layer 7-T (Subject Device)	Ad-Tech Subdural Electrodes (K191186)	Comment
Contact Diameter	0.05-0.5mm	4,5mm	The range of contact diameters is changed to accommodate the higher density electrodes implied by a larger number of contacts per the same electrode surface area. Electrode to tail contact impedance is designed to meet applicable specification. Potential impacts of charge density are controlled by controlled charge density limits for the exposed electrode contact diameter (≤50 µC/cm2).
Electrode Spacing	400µm	10 mm	The electrode spacing is changed to accommodate the higher density implied by a larger number of contacts per the same electrode surface area. Electrode to tail contact impedance is designed to meet applicable specification. Potential impacts of charge density are controlled by controlled charge density limits for the exposed electrode contact diameter (≤50 µC/cm2).

Feature	Layer 7-T (Subject Device)	Ad-Tech Subdural Electrodes (K191186)	Comment
Electrode Film Material	Polyimide	Silicone	The Layer 7-T has undergone complete biocompatibility testing and GLP implantation testing. All results passed. The polyimide material is a known material that has been used in other FDA-cleared cortical arrays (NeuroOne K192764).
Sterilization	Ethylene Oxide	Ethylene Oxide	Same

Performance Data:

The Layer 7-T has undergone complete non-clinical testing to demonstrate that it is as safe and effective as the predicate which includes Sterilization Validation, Packaging Validation, Shelf Life testing, Biocompatibility testing per ISO 10993-1, Electrical Safety and EMC testing, Performance testing for dimensional measurement, durability, electrochemical performance, platinum dissolution testing, Signal-to-Noise Ratio Testing, Reliability Testing, EEG system compatibility testing and human factors testing. The tests and their respective standards (if applicable) are listed below. All testing passed as expected.

Test	Methods	Results
Dimensional Measurements	Confirm hardware specifications by measurement and visual assessment.	Pass
Durability	Mechanical testing, to verify the electrode, lead bodies, and connectors function safely and effectively under normal use conditions.	Pass
Electrochemical Performance	I**mpedance testing** conducted to **verify conductive properties appropriate for** the device **intended use.** **Testing** verifies **electrical continuity through the** proposed device.	Pass

Platinum Dissolution Testing	Quantify the level of platinum released **following** a **stimulation protocol selected in a worst case clinically relevant manner**.	Pass
Signal-to-Noise Ratio Testing	Comparative Signal-to-Noise Ratio testing of Layer 7-T SNR to the predicate.	Pass
Reliability	Evaluate electrochemical and physical properties following accelerated aging.	Pass
EEG system compatibility	**Verification of** signal **acquired following cycling** of **connector**.	Pass
Packaging Shelf Life	ASTM F2096-11(2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials	Pass
Sterilization	ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization	Pass

	process for medical devices ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices	

Biocompatibility

Layer 7-T is classified as blood contacting implant with prolonged contact during clinical use (< 24 hours to 30 days). The Layer 7-T was evaluated according to the FDA guidance (2023) "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The following biocompatibility endpoints were assessed for the Layer 7-T:

- Cytoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Genotoxicity
- Implantation Testing
- Hemolysis (Indirect Contact)
- Chemical characterization and a toxicological risk assessment was conducted to evaluate risks associated with subacute and subchronic toxicity.

Results support the biocompatibility of the Layer 7-T.

Electrical Safety and Electromagnetic Compatibility

The test reports address the basic safety evaluation (which includes electrical safety testing) per the FDA consensus standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, and IEC 60601-1-6:2010, AMD1:2013, AMD2:2020. Additionally, EMC testing was conducted per IEC 60601-1-2:2014+A1:2020, EN 60601-1-2015+A1:2021, IEC 80601-2-49:2018, and IEC TR 60601-4-2:2024 and passed the applicable clauses. The results support the electrical safety and EMC of the device.

Human Factors

Usability has been validated to support the safety and effectiveness of the device for their intended users and environment. This process was completed in accordance with the principles outlined in the "Applying Human Factors and Usability Engineering to Medical Devices" guidance. All evaluations have been performed according to ANSI AAMI HE75:2009 Human Factors Engineering – Design of Medical Devices

Animal Testing

A Good Laboratory Practices (GLP) animal study was conducted to evaluate the Layer 7 cortical electrode array implanted into the subdural space of the brain. This study consisted of 16 female Göttingen swine divided into two cohorts, a 1-week implant duration and a 6-week implant duration. Neurological evaluation gross and microscopic analysis, were conducted, and the results from animals implanted with the Layer 7 cortical electrode array were compared to those from control animals implanted with the AD-TECH subdural strip electrodes. No adverse events were related specifically to the Layer 7 Cortical Electrode Array were identified in the study. The biocompatibility of the test article was confirmed based on the clinical status of the animals in the survival period and the results of the postmortem neuropathology examination. The pathology evaluation of this study revealed that both the test article and the control (predicate AD-TECH subdural strip electrodes) device had no evidence of ongoing neurotoxicity in the tested conditions, and elicited a similar cortical inflammatory response, which subsided in both groups by 6 weeks compared to the 1-week group.

The results from bench testing and animal studies demonstrate that the safety and performance of the Layer 7-T is similar to that of the predicate device, Ad-Tech Subdural Electrodes (K191186).

Conclusions

The subject Layer 7-T is as safe and effective as the predicate Ad-Tech Subdural Electrodes. The Layer 7-T has the same intended uses and similar indications for use, technological characteristics, and principles of operation as the predicate device. The minor differences in indications for use do not alter the intended use of the device and do not affect its safety and effectiveness when used as indicated. In addition, the technological differences between the Layer 7-T and its predicate device raise no new questions of safety or effectiveness. The performance data outlined above demonstrate that the Layer 7-T is as safe and effective as the Ad-Tech Subdural Electrodes. Thus, the Layer 7-T is substantially equivalent to the Ad-Tech Subdural Electrodes.