



January 25, 2020

Ad-Tech Medical Instrument Corporation
Gary Syring
Compliance Manager/Regulatory Specialist
400 West Oakview Parkway
Oak Creek, Wisconsin 53154

Re: K191186

Trade/Device Name:

- 1) Subdural Strip/Intraoperative Strip Electrode,
- 2) Subdural Grid/Intraoperative Grid Electrode,
- 3) Dual-Sided Interhemispheric Subdural Electrode,
- 4) Multi-Strip and Split Grid Subdural Electrode,
- 5) Intraoperative Mapping Grid Subdural Electrode

Regulation Number: 21 CFR 882.1310

Regulation Name: Cortical Electrode

Regulatory Class: Class II

Product Code: GYC

Dated: December 23, 2019

Received: December 27, 2019

Dear Gary Syring:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

510(k) Number (if known)

K191186

Device Name

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

Indications for Use (Describe)

The Ad-Tech Subdural Electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Dual-Sided Interhemispheric, Multi-Strip 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.

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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Traditional 510(k) Summary – K191186

This 510(k) summary was prepared to provide an understanding of the basis for the determination of substantial equivalence in accordance with the requirements 21 CFR 807.92.

Submitter's Name: Ad-Tech Medical Instrument Corporation
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Oak Creek, WI 53154
Phone: (262) 634-1555

Contact Person: Suzie Towers, Director, Quality Assurance, Regulatory Affairs
Contact Telephone: 262-634-1555

Date Summary Prepared: January 24, 2020

Device Trade Name: Subdural Electrode
-Strip/Intraoperative Strip,
-Grid/Intraoperative Grid,
-Dual-Sided Interhemispheric,
-Multi-Strip and Split Grid, and
-Intraoperative Mapping Grid

Common Name: Subdural Electrode

Classification Name: Cortical Electrode
21 CFR 882.1310
Product Code: GYC Class II

Predicate Devices: K053363 Subdural Electrode
-Dual-Sided Interhemispheric,
-Grid,
-Intraoperative,
-Strip, and
-Wyler

Purpose of Submission

Both the predicate Subdural Electrodes and the Subdural Electrodes under review are characterized by physical features that describe the characteristics of the variations. Modification of available Subdural Electrode Product Family features addressed by this 510(k) submission are summarized in the table below.

Subdural Electrode Product Family Feature Modifications		
Modification	Substantial Equivalence Discussion	Scientific Methods for Evaluating New/Different Characteristics
Product commercial name changes	From: Strip Subdural Electrodes, To: Subdural Strip From: Intraoperative Subdural Electrodes, To: Intraoperative Strip Electrodes From: Grid Subdural Electrodes (Wyler Electrodes), To: Grid Electrode From: Intraoperative Subdural Electrodes To: Intraoperative Grid Electrode	The naming convention modifications clarify Subdural Strip Electrodes can be used intraoperatively. This change is consistent with the predicate's intended use. The predicate 510(k) indicated Strip Subdural and Grid Subdural electrodes could be used intraoperatively.
	From: Grid Subdural Electrodes, Intraoperative Subdural Electrodes To: Intraoperative Mapping Grid Electrodes	This change is a renaming of the Grid subdural electrodes, Intraoperative Subdural Electrodes. "Mapping" is a clinical term applied to the use of subdural electrodes for stimulation and recording of locations on the brain surface. This change is consistent with the indications for use of Subdural Electrodes, which is not modified by the submission.
Addition of Multi-Strip and Split Grid subdural electrode variations	The Multi-Strip and Split Grid Electrode variations embody individual Strip and Grid Subdural Electrodes into one assembly, combining the Tails to support ease of subcutaneous tunneling, see Figure 1. The same materials and manufacturing processes are applied to create these electrodes as were applied in the predicate submission. As a convenience to the user, the multiple tails from each electrode are placed together into one tube of electrode tails.	Confirmation of the electrical pathway from the connector on the distal end of electrode to the electrode contact is verified for proper resistance and no cross connect to another electrode contact or connector contact.
Intraoperative Mapping Grid Subdural Electrode contacts increased from 5 to 6 contacts.	The Intraoperative Mapping Grid Subdural Electrode variations embodies 1 to 6 single electrode contacts into one assembly, see Figure 2. The electrode tail terminates in a 1.5 mm, recessed female connector for interface to the user's equipment. The same materials and manufacturing processes are applied to create these electrodes as those materials and manufacturing processes that were used for the predicate device.	Confirmation of the electrical pathway from the connector on the distal end of electrode to each electrode contact is verified for proper resistance and no cross connect to another electrode contact or connector contact.
The maximum number of Subdural Electrode Contacts is increased from 128 to 256 contacts.	The same electrode contact material and manufacturing processes are applied to fabricate the 256 contact electrode. The silicone substrate body surface area of the electrode is not modified, the higher electrode contact count is accomplished with the same surface area of Subdural Electrode body.	Confirmation of the electrical pathway from the connector on the distal end of electrode to the electrode contact is verified for proper resistance and no cross connect to another electrode contact.
Subdural Electrode contact spacing	The center to center spacing between electrode contacts is modified from: 1 to 10 mm, to: 1 to 20 mm. It is user	The same manufacturing processes applied with application of the electrodes to a build template that

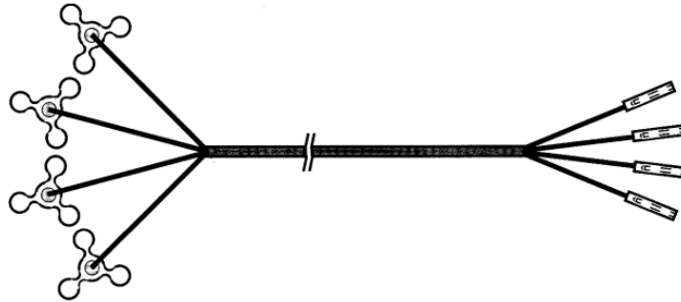


Figure 2: Intraoperative Mapping Grid Subdural Electrode

Device Description

The device under review is a family of Subdural Electrodes. These electrodes provide surface brain contact to support recording, monitoring and stimulation from user supplied equipment.

The family of Subdural Electrodes under review are used under the direction of neurosurgeons and other skilled physicians to support their clinical needs for subdural electrodes on the brain. Based upon the needs of their clinical practice and particular patients, various 2-dimensional geometric shapes (length and width) resulting in variations of Subdural Electrode body shapes and orientation configurations are necessary.

All variations of Subdural Electrodes under review consist of the same materials and fundamental design as the predicate Subdural Electrodes. Either round discs or rectangular electrode contact material are sandwiched between two layers of silicone substrate electrode body material. The brain contacting side of the silicone substrate body has material removed to expose an amount of electrode contact surface area. The subdural electrode wires between the electrode contact and connector contacts at the most distal end of the subdural electrode tail pass through a tube for interface with the user's equipment.

Intended Use of the Device

The Ad-Tech Subdural Electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Dual- Sided Interhemispheric, Multi-Strip 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.

Ad-Tech's Subdural Electrode intended use is modified the current trade names of the Subdural Electrodes. This is the only information in the intended use modified by this 510(k) submission. This modification has no impact on the actual intended use of the device.

Summary of Technological Characteristics

The fundamental technical characteristics of the Subdural Electrodes are not affected by this submission. Fundamentally the Subdural Electrodes are a conductor of the biopotential signals from the surface of the brain to the user's equipment and as applicable, conductors of the stimulation energy from the user's equipment to the surface of the brain.

The following table provides a side-by-side comparison of the Subdural Electrodes to the predicate devices applied to support this pre-market notification.

Substantial Equivalence Technical Characteristics			
Feature	Subdural Electrodes (Under Review)	Subdural Electrodes (Primary Predicate K053363)	Comment
Indications for Use	The Ad-Tech Subdural Electrodes (Strip/Intraoperative Strip, Grid/Intraoperative Grid, Dual-Sided Interhemispheric, Multi-Strip 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 Ad-Tech Subdural Electrodes (Dual-Sided Interhemispheric, Grid, Intraoperative, Strip, Wyler) 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.	Update list of trade names.
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 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.	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	Yes	Only sterilized electrodes are available.
Environment of	Operating rooms and temporary	Operating rooms and temporary	Same

Substantial Equivalence Technical Characteristics			
Feature	Subdural Electrodes (Under Review)	Subdural Electrodes (Primary Predicate K053363)	Comment
Use	monitoring	monitoring	
Duration of Use	< 30 days	< 30 days	Same
Electrode Body surface area	$\leq 138 \text{ cm}^2$	$\leq 138 \text{ cm}^2$	Same The subdural electrodes consist of an electrode contact between two layers of silicone material. The silicone material defines Electrode Body surface area.
Electrode Contact Material	Platinum/Iridium or Stainless Steel	Platinum/Iridium or Stainless Steel	Same
Maximum Stimulation Charge Density	$\leq 30 \mu\text{C}/\text{cm}^2$	Not indicated in labeling	Clarification of stimulation charge density limits for brain tissue, as established in K152769 (Surgical Nerve Stimulator).

Performance Tests to Demonstrate Substantial Equivalence

To establish the technical equivalency of the Subdural Electrodes, evaluations were conducted to confirm compliance with performance requirements, including:

Test	Summary of Requirement, Evaluation	Result
Electrical Resistance	Measure electrical resistance from the electrode contact to connector. Verification of electrical resistance from electrode contact to connector meet specification, no electrical contact or connector cross connects to another electrode contact or connector.	Pass
Dimensional Characteristics	Dimensional requirements are met by manufacturing. Verification of the dimensional characteristics, electrode contact placement is confirmed using the same manufacturing methods and processes as the predicate electrodes.	Pass
Stimulation effect	Stimulation at $30 \mu\text{C}/\text{cm}^2$ does not affect the electrodes. Verification that under the anticipated duration of electrical stimulation at the maximum limit does not affect the electrode resistance.	Pass
Shelf Life	Confirmation of subdural electrode functional performance and sterile barrier pouch integrity (seal peel per ASTM F88 and bubble leak per ASTM F2096) after 2-year aging and simulated distribution per ASTM 4169-16 and bubble leak (ASTM F2096) after accelerated aging (ASTM F1980) and real-following time aging of two years and after simulated distribution by ASTM 4169-16. Verified by application of referenced standards and conformance with specifications.	Pass

Test	Summary of Requirement, Evaluation	Result
Sterility	EO sterilization of the subject device was validated according to ISO 11135:2014 to demonstrate that it is provided with a minimum sterility assumed level (SAL) of 10 ⁻⁶ .	Pass
Biocompatibility	N/A Biocompatibility was not provided to support a determination of substantial equivalence for this submission because material and manufacturing processes have not been changed from those were cleared with the predicate device.	N/A

Clinical data was not provided to support a determination of substantial equivalence.

Conclusion

Based on the intended use, technological characteristics as compared to the predicate, and performance testing, the subdural electrode is substantially equivalent to the predicate device.