October 2, 2021

DIXI Medical
℅ Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K201931
Trade/Device Name: DIXI Medical Intraoperative Subdural Electrodes (Strips and Grids)
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC
Dated: September 1, 2021
Received: September 2, 2021

Dear Cindy Domecus:

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,

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)*
K201931

Device Name
DIXI Medical Intraoperative Subdural Electrodes (Strips and Grids)

Indications for Use *(Describe)*
The DIXI Medical Intraoperative Subdural Electrodes (Strips and Grids) are intended for intraoperative use for less than or equal to 24 hours with recording and stimulation equipment for the recording and stimulation of electrical signals on the surface level of the brain. The recording of electrical activity supports 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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510(k) Summary

I. SUBMITTER

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Date Prepared
September 24, 2021

II. DEVICE

Name of Device:	DIXI Medical Intraoperative Subdural Electrodes (Strips and Grids)
Common or Usual Name:	Intraoperative Subdural Electrode
Classification Name:	21 CFR §882.1310 Cortical Electrode
Regulatory Class:	II
Product Code:	GYC

III. PREDICATE DEVICE

The predicate device is the Ad-Tech Medical Instrument Corporation's Subdural Cortical Electrodes (K191186). There have been no recalls for the predicate device.

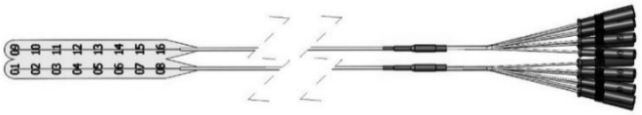
IV. DEVICE DESCRIPTION

The DIXI Medical Intraoperative Subdural Electrode (Strips and Grids) is an intra-cranial electrode used intraoperatively on the surface of the brain. The device is designed for

electroencephalography (EEG) recording and brief stimulation for brain mapping purposes.

The DIXI Medical Intraoperative Subdural Electrode consists of circular contacts sandwiched between two layers of silicone substrate. The brain contacting side of the silicone substrate body has material removed to expose an amount of contact surface area. Insulated wires extend from each contact through a flexible tube which terminates in connectors for direct connection to user's equipment.

A summary of the subject device configurations is provided below.

Product Reference	**Configuration**	**Schematic drawing**
C10-08AIOM	1 strip x 8 contacts Contacts numbered from 1 to 8	
C10-16AIOM	2 strip x 8 contacts Contacts numbered from 1 to 16	
C10-06BIOM	1 strip x 6 contacts Contacts numbered from 1 to 6	
C10-12BIOM	2 strip x 6 contacts Contacts numbered from 1 to 12	
C10-04CIOM	1 strip x 4 contacts Contacts numbered from 1 to 4	

Product Reference	Configuration	Schematic drawing
C10-08CIOM	2 strip x 4 contacts Contacts numbered from 1 to 8	
C10-16CIOM	4 strip x 4 contacts Contacts numbered from 1 to 16	

V. INDICATIONS FOR USE

The Indications for Use for the subject and predicate devices are noted below.

DIXI Medical Intraoperative Subdural Electrodes SUBJECT DEVICE	AD-TECH Subdural Cortical Electrodes PREDICATE DEVICE, K191186
The DIXI Medical Intraoperative Subdural Electrodes (Strips and Grids) are intended for intraoperative use for less than or equal to 24 hours with recording and stimulation equipment for the recording and stimulation of electrical signals on the surface level of the brain. The recording of electrical activity supports brain mapping.	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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The predicate device clearance is for a family of electrodes, whereas the subject device is for a single electrode type. As such, the below comparisons are between the subject device and the corresponding electrode type within the predicate device family of electrodes (i.e., the Intraoperative Strip and Intraoperative Grid).

Both the subject and predicate devices are intended for use with recording and stimulation equipment for the recording and stimulation of electrical signals at the surface level of the brain. At a high level, the subject and predicate devices are based on the following same technological elements:

- Both the subject and predicate device are subdural cortical electrodes for the same duration of use in the same environment of use.
- Both the subject and predicate device are provided sterile and for single-use only and use the same method of sterilization.
- Both the subject and predicate device have a maximum stimulation charge density of $\leq$ 30 $\mu C/cm^2$.
- The subject and predicate device have the same contact spacing, maximum number of contacts per electrode cable and diameter of electrode cable.

The following technological differences exist between the subject and the Intraoperative Strip and Intraoperative Grid predicate devices:

- The number of contacts per electrode is similar. The number of contacts for strips is the same. The maximum number of contacts for predicate Intraoperative Grid is unknown but, in any case, the number of contacts for the subject device is within the range of the number of contacts for the predicate device.
- The contact materials are similar but not identical; the subject device is stainless steel only, whereas the predicate device includes 90:10 Platimum:Iridium not present in the subject device.
- The contact external diameter is similar but not identical; the subject device is 6.0mm-diameter only. The contact exposure diameter is similar but not identical. The subject device exposure diameter is within the range of exposure diameter for the predicate device.
- Both the subject and predicate device cabling terminate in a 1.5mm female socket, but there is the option with the predicate device to connect to a patient cable.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Nonclinical Testing

The nonclinical testing included in the table below was conducted on subject devices, on baseline and aged devices. Aged devices underwent three sterilization cycles, accelerated aging equivalent to real-time ageing of 5 years (ASTM F1980), extreme climatic conditions (ASTM D4332) and tests of transport (ASTM D4169).

Test Performed	**Tested Device Reference**	**Objective**	**Conclusion**
Dimensional Characteristics	C10-04CIOM C10-08AIOM	Verification of electrodes dimensional characteristics	Pass

Test Performed	Tested Device Reference	Objective	Conclusion
Electrical Characteristics	C10-04CIOM C10-08AIOM	Verification of the electrodes ability to transmit a stimulation signal	Pass
		Verification of the electrodes resistance to a stimulation signal under worst case charge density condition	Pass
		Verification of the electrodes resistance to a stimulation signal under worst case current condition	Pass
		Verification of the electrodes dielectric strength	Pass
		Verification of electrodes stability under conditions of use (absence of corrosion)	Pass
Mechanical Characteristics	C10-04CIOM C10-08AIOM	Verification of the resistance to torsion of the active part and silicon sheath	Pass
		Verification of electrodes resistance to bending	Pass
		Verification of electrodes resistance to traction	Pass

Biocompatibility Testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA's September 2020 guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff*. The biocompatibility evaluation included the following tests and results:

Test	Tested Device Reference	Result	Conclusion
Cytotoxicity	C10-08AIOM	Test 1: Percent viability of test article was 93.9% of reagent control. Test 1: Percent viability of test article was 98.6% of reagent control. Test 3: Percent viability of test article was 88.5% of reagent control.	Non-cytotoxic
Sensitization	C10-16CIOM	Topical application of the 0.9% sodium chloride extract and the sesame oil extract did not induce delayed sensitization in the guinea pig.	Non-sensitizer
Intracutaneous reactivity	C10-16CIOM	Difference between each test extract overall mean score and corresponding control blank overall mean score was lower than 1.0 (0.0 for the 0.9% sodium chloride extract and sesame oil test extracts).	Non-irritant
Pyrogenicity	C10-16CIOM	No rabbit showed an individual temperature rise higher or equal to 0.5°C above its initial temperature.	Non-pyrogenic
Indirect (extract) hemolysis	C10-16CIOM	Mean hemolytic index for test article extract was of 0.0%.	Non-hemolytic
Acute Systemic Toxicity	C10-16AIOM	No evidence of significant systemic toxicity or mortality after test article extracts injection.	Non-toxic

The contact classification for the subject device is an external communicating device with tissue/bone contact and cerebrospinal fluid (CSF) contact for a limited (≤24 hours) duration.

Sterilization and Shelf-Life Testing

The subject device is sterilized using Ethylene Oxide to a SAL = 10^{-6}. A shelf-life of 5 years has been established based on accelerated and real-time aging.

VIII. CONCLUSIONS

The Indications for Use for the subject device is a subset of the Indications for Use for the predicate device, and the differences in technological characteristics do not raise new or different questions of safety and effectiveness, with the non-clinical and biocompatibility testing performed demonstrating the continued effectiveness of the subject device as compared to the predicate device.