November 18, 2021

Steven Plymale
CEO
Dixi Neurolab, Inc.
145 Howland Pines Drive
Oxford, MI 48371

Re: K202087
Trade/Device Name: DIXI Medical Microdeep Micro-Macro Depth Electrodes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: October 20, 2021
Received: October 22, 2021

Dear Steven Plymale:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202087

Device Name
DIXI Medical Microdeep® Micro-Macro Depth Electrodes

Indications for Use *(Describe)*
The DIXI Medical Microdeep® Micro-Macro Depth Electrodes are intended for temporary (<30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level 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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510(k) Summary

I. SUBMITTER

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Date Prepared
Oct. 20, 2021

II. DEVICE

Name of Device:	DIXI Medical Microdeep® Micro-Macro Depth Electrode
Common or Usual Name:	Depth Electrode
Classification Name:	21 CFR §882.1330 Depth Electrode
Regulatory Class:	II
Product Code:	GZL

III. PREDICATE DEVICE

The predicate device is the Ad-Tech Medical Instrument Corporation's Macro Micro Depth Electrodes (K163355). The DIXI Medical Microdeep® Depth Electrode (K170959) was a reference device for this submission.

IV. DEVICE DESCRIPTION

The Microdeep® Micro-Macro Depth Electrode is a single patient use, sterile and disposable device. The Microdeep® Micro-Macro Depth Electrode is invasive as it is placed in contact with nerve tissue (brain) and must only be used during an SEEG procedure with Anchor Bolts. The Microdeep® Micro-Macro Depth Electrode is intended to connect to the user's recording, monitoring and stimulation equipment using the Connection System. This product is intended to be used only by physicians in the area of biopotential recording, monitoring and stimulation / response studies who are trained in intracranial neurophysiology.

The DIXI Medical Microdeep® Micro-Macro Depth Electrode is comprised of the following components:

- Macro-contacts - located on the outside of the device.
- Micro-contacts - sit flush at the surface of the device between the macro electrodes.
- Microdrive for micro-contacts
- Cap
- Connectors for micro and macro-contacts

V. INDICATIONS FOR USE

The DIXI Medical Microdeep® Micro-Macro Depth Electrodes are intended for temporary (<30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level 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 technological characteristics comparing to the predicate device are outlined in the Substantial Equivalent table.

Attribute	DIXI Medical Microdeep® Micro-Macro Depth Electrodes (Subject Device)	Ad-Tech Medical Instrument Corporation Macro Micro Depth Electrodes (Predicate device K163355)	DIXI Medical Microdeep Depth Electrode (Reference Device K170959)
Regulation Number	21 CFR §882.1330	21 CFR §882.1330	21 CFR §882.1330
Regulation Name	Depth electrode	Depth electrode	Depth electrode
Regulatory Class	Class II	Class II	Class II
Product Code	GZL	GZL	GZL
Indications for Use	The DIXI Medical Microdeep® Micro-Macro Depth Electrodes are intended for temporary (<30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of epileptogenic foci and brain mapping.	The AD-TECH Depth Electrodes (Depth Electrodes, Foramen Ovale Depth Electrodes, Macro Micro Depth Electrodes, Spencer Probe Depth Electrodes, Wyler Sphenoidal Depth Electrodes) are intended for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports definition of the location of	The DIXI Medical Microdeep Depth Electrodes are intended for temporary (<30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

Attribute	DIXI Medical Microdeep® Micro-Macro Depth Electrodes (Subject Device)	Ad-Tech Medical Instrument Corporation Macro Micro Depth Electrodes (Predicate device K163355)	DIXI Medical Microdeep Depth Electrode (Reference Device K170959)
		epileptogenic foci and brain mapping.	
Environment of Use	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations
Provided Sterile	Yes	Yes	Yes
Method of sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
Single Use, disposable	Yes	Yes	Yes
Duration of Use	< 30 days	< 30 days	< 30 days
Maximum Stimulation Charge Density	≤ 30 μC/cm²	≤ 30 μC/cm²	≤ 30 μC/cm²
Electrode Characteristics			
General characteristic	One piece design: depth electrode that has electrical macro-contacts collars placed on the outside and micro-contacts cut flush at the surface, between macro-contacts, which can be released	Two kinds of Macro Micro Depth Electrodes: 1. BEHNKE FRIED DEPTH ELECTRODES, two piece design: - Macro portion: depth electrode that has electrical macro-contacts collars placed on the outside and an inner lumen throughout the entire length - Micro portion: wire bundle	One piece design: depth electrode that has electrical macro-contacts collars placed on the outside, no micro-contacts

Attribute	DIXI Medical Microdeep® Micro-Macro Depth Electrodes (Subject Device)	Ad-Tech Medical Instrument Corporation Macro Micro Depth Electrodes (Predicate device K163355)	DIXI Medical Microdeep Depth Electrode (Reference Device K170959)
		(micro-contacts) that passes through the inner lumen of the macro-electrode 2. MACRO-MICRO DEPTH ELECTRODES: one piece design: depth electrode that has electrical macro-contacts collars placed on the outside and micro-contacts cut flush at the surface, between macro-contacts	
Removable stylet in the electrode	No	Yes	No
Contacts Material	Platinum/Iridium 90/10 (Macro-contact) Tungsten (Micro-contact)	Platinum (Macro-contact) Platinum/Iridium (Micro-contact)	Platinum/Iridium 90/10 (Macro-contact)
Electrode body diameter (brain contact)	0.8 mm (Macro-contact) 20 microns (Micro-contact)	1.3 mm (Macro-contact) 38 to 51 microns (Micro-contact)	0.8 mm (Macro-contact)
Number of electrode contacts	From 6 to 9 (Macro-contact) From 8 to 12 (Micro-contact)	From 6 to 12 (Macro-contact) From 8 to 24 (Micro-contact)	From 5 to 18 (Macro-contact)
Electrode contact length (along body of the electrode)	2 mm (Macro-contact)	1.57 mm (Macro-contact)	2 mm (Macro-contact)

Attribute	DIXI Medical Microdeep® Micro-Macro Depth Electrodes (Subject Device)	Ad-Tech Medical Instrument Corporation Macro Micro Depth Electrodes (Predicate device K163355)	DIXI Medical Microdeep Depth Electrode (Reference Device K170959)
Overall length	~ 400 mm	≤ 660 mm	≤ 1050 mm
Device Accessories – Anchor Bolt			
Product Code	GZL	GZL	GZL
Regulation Number	21 CFR §882.1330	21 CFR §882.1330	21 CFR §882.1330
Regulatory Class	II	II	II
Material	Titanium alloy Ti6Al4V (ELI, ASTM F136)	Titanium Silicone (inner lumen gasket) Parylene	Titanium alloy Ti6Al4V (ELI, ASTM F136)
Length	From 15 mm to 35 mm	From 13 mm to 26 mm	From 15 mm to 35 mm
Required Drill Hole Diameter	2.1 mm	2.4 mm or 2.8 mm	2.1 mm
Compatible Depth Electrode Body Diameter	0.8 mm	0.86 mm to 1.3 mm	0.8 mm
Attachment onto the skull	Threaded into a pre-drilled hole in the skull	Threaded into a pre-drilled hole in the skull	Threaded into a pre-drilled hole in the skull
Anchor bolt placement	Long Screwdriver	Anchor bolt placement wrench	Long Screwdriver
Anchor bolt removal	Wrench and Short Screwdriver	Anchor bolt removal wrench	Wrench and Short Screwdriver
Implantation duration	Up to 30 days	Up to 30 days	Up to 30 days
Single use	Yes	Yes	Yes

Attribute	DIXI Medical Microdeep® Micro-Macro Depth Electrodes (Subject Device)	Ad-Tech Medical Instrument Corporation Macro Micro Depth Electrodes (Predicate device K163355)	DIXI Medical Microdeep Depth Electrode (Reference Device K170959)
Method of sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
Device Accessories			
List of Accessories	Instrument guide, Bone starter, Sliding Ruler, Coagulation Electrode and Stop, Flat Screwdriver (for stop), Drill and Stop, Long Screwdriver, Anchor Bolt, Marking Rod, Cap for Anchor Bolt, Depth Report device, Stylet, Stop, Sheath Holder, Extension cable, Adapter and Connection cable, and Wrench and Short Screwdriver for Anchor Bolt.	Guide, Channeled Ruler, Drill Bit with Stop and Wrench, Anchor placement/removal Wrench, Anchor Bolt, Obturator and Cabrio and Tech-Attach Connection Systems	Instrument guide, Bone starter, Sliding Ruler, Coagulation Electrode and Stop, Flat Screwdriver (for stop), Drill and Stop, Long Screwdriver, Anchor Bolt, Marking Rod, Cap for Anchor Bolt, Depth Report device, Stylet, Stop, Extension cable, Adapter and Connection cable, and Wrench and Short Screwdriver for Anchor Bolt.
Single-Use Accessories	Coagulation Electrode and Stop, Drill and Stop, Anchor Bolt, Cap for Anchor Bolt, Stylet, Sheath Holder	Drill Bit with Stop and Wrench, Anchor Bolt and Obturator	Coagulation Electrode and Stop, Drill and Stop, Anchor Bolt, Cap for Anchor Bolt, Stylet
Method of Sterilization for Single Use Accessories	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Reusable Accessories	Instrument guide, Bone starter, Sliding Ruler, Flat Screwdriver (for stop), Long Screwdriver, Marking Rod,	Guide, Channeled Ruler, Anchor placement/removal Wrench, and Cabrio and Tech-Attach Connection Systems	Instrument guide, Bone starter, Sliding Ruler, Flat Screwdriver (for stop), Long Screwdriver, Marking Rod,

Attribute	DIXI Medical Microdeep® Micro-Macro Depth Electrodes (Subject Device)	Ad-Tech Medical Instrument Corporation Macro Micro Depth Electrodes (Predicate device K163355)	DIXI Medical Microdeep Depth Electrode (Reference Device K170959)
	Depth Report Device, Stop, Extension Cable, Adapter, Connection Cable, Wrench and Short Screwdriver for Anchor Bolt		Depth Report Device, Stop, Extension Cable, Adapter, Connection Cable, Wrench and Short Screwdriver for Anchor Bolt
Method of Sterilization for Reusable Accessories	Steam Sterilization (with the exception of the Adapter, which does not require sterilization)	Unknown (except for Cabrio and Tech-Attach Connection Systems: Ethylene Oxide or Sterrad)	Steam Sterilization (with the exception of the Adapter, which does not require sterilization)

VII. NON-CLINICAL TESTING

DIXI Medical has performed the following non-clinical laboratory testing to determine substantial equivalence.

Test	Summary of Verifications	Result
Dimensional Characteristics	Verification of electrodes dimensional characteristics	Pass
Mechanical characteristics	- Verification of electrode microdrive functioning - Verification of electrode water tightness - Verification of cap maintenance on the electrode sheath - Verification of the antirotation function of electrode cap - Verification of tensile strength of electrode macro-contacts	Pass
Electrical characteristics	- Verification of the electrical characteristics (contacts continuity, contacts resistance, absence of short-circuit, insulating resistance) - Verification of the electrode integrity and electrical functionality after stimulation under worst case charge density	Pass
Device integrity	- Verification of the absence of alteration of the packaging - Verification of the absence of alteration of the electrode	Pass
Comparative Testing	- Comparative test of the tensile strength of the micro-contacts between the predicate device and the subject device - Verification of the integrity and the mechanical functionality of the predicate device and the subject device after clinical simulation of use	Pass

VIII. BIOCOMPATIBILITY TESTING

The contact classification for the DIXI Medical Microdeep® Micro-Macro Depth Electrode component of the subject device is an external communicating device with tissue/bone and cerebrospinal fluid contact for a prolonged duration (>24 hours to 30 days). The biocompatibility evaluation for the subject device was conducted in accordance with ISO 10993-1:*2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and in accordance with FDA 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 results of biocompatibility testing included in

the table below demonstrate that the device meets biological safety requirements per ISO 10993-1 for externally communicating devices with tissue/bone and cerebrospinal fluid contact and prolonged duration (>24 hours to 30 days.).

Test	Standard	Result
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Sensitization	ISO 10993-10	Non-sensitive
Irritation or intracutaneous reactivity	ISO 10993-10	Negligible irritation
Acute systemic toxicity	ISO 10993-11	Non-toxic
Material-mediated pyrogenicity	USP	Non-pyrogenic
Sub-acute toxicity	ISO 10993-11	Non-toxic
Genotoxicity – Mouse Lymphoma Assay	OECD guideline No. 490 and ISO 10993-3	Non-genotoxic
Genotoxicity – Bacterial Reverse Mutation	OECD guideline No. 471 and ISO 10993-3	Non-genotoxic
Indirect (extract) hemolysis	ASTM F756 and ISO 10993-4	Non-hemolitic
Implantation and neurotoxicity	ISO 10993-6	No or minimal reaction

IX. STERILIZATION AND SHELF-LIFE TESTING

The subject device is sterilized using Ethylene Oxide. The sterilization validation has been performed in accordance with the principles of *ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices*. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The device meets EO residuals per ISO 10993-7.

A shelf-life of 4 years has been established based on accelerated and real-time aging.

X. CONCLUSIONS

The subject and predicate device share the same intended use – for temporary (< 30 days) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the nonclinical performance data submitted in the 510(k) demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device.