November 5, 2025

Beijing Sinovation Medical Technology Co., Ltd.
Lina Wang
RA Specialists
Room 218, 2nd Floor, Building 1, No. 1, Hangfeng Road
Fengtai District
Beijing, 100070
China

Re: K250363
Trade/Device Name: Depth Electrode (RSDE-08); Depth Electrode (RSDE-10); Depth Electrode (RSDE-12); Depth Electrode (RSDE-14); Depth Electrode (RSDE-16); Depth Electrode (RSDE-16F); Depth Electrode (RSDE-08S); Depth Electrode (RSDE-10S); Depth Electrode (RSDE-12S); Depth Electrode (RSDE-14S); Depth Electrode (RSDE-16S); Depth Electrode (RSDE-16G); Depth Electrode (RSDE-18); Depth Electrode (RSDE-18F); Depth Electrode (RSDE-18T); Depth Electrode (RSDE-20); Depth Electrode (RSDE-20F); Depth Electrode (RSDE-20T); Guidance Screw (DX-20); Guidance Screw (DX-25); Guidance Screw (DX-30); Guidance Screw (DX-35); Connection Cable (LX-12); Connection Cable (LX-16); Connection Cable (LX-20); Connection Cable (LX-S); Connection Cable (LX-RF2)
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: December 3, 2024
Received: February 10, 2025

Dear Lina Wang:

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,

Patrick Antkowiak -S

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250363

Please provide the device trade name(s).

Depth Electrode (RSDE-08);
Depth Electrode (RSDE-10);
Depth Electrode (RSDE-12);
Depth Electrode (RSDE-14);
Depth Electrode (RSDE-16);
Depth Electrode (RSDE-16F);
Depth Electrode (RSDE-08S);
Depth Electrode (RSDE-10S);
Depth Electrode (RSDE-12S);
Depth Electrode (RSDE-14S);
Depth Electrode (RSDE-16S);
Depth Electrode (RSDE-16G);
Guidance Screw (DX-20);
Guidance Screw (DX-25);
Guidance Screw (DX-30);
Guidance Screw (DX-35);
Connection Cable (LX-12);
Connection Cable (LX-16);
Connection Cable (LX-20);
Connection Cable (LX-S);
Connection Cable (LX-RF2)

Please provide your Indications for Use below.

The Depth Electrode is intended for temporary (less than 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

I.Submitter

BEIJING SINOVATION MEDICAL TECHNOLOGY CO.,LTD.
Room 218, 2nd Floor, Building 1, No. 1, Hangfeng Road, Fengtai District, Beijing, P.R. China： 100070
Tel： +86 10 80481789
Contact person： Lina Wang
Date Prepared： Oct 26, 2025

II. Device

Name of Device: Depth Electrode
Common or User name: Depth Electrode
Classification Name: Depth Electrode(21 CFR 882.1330)
Regulatory Class: II
Product Code: GZL

III. Predicate device

Predicate Device: Evo@sEEG System
Predicate 510(K) number: K222404
Manufacture:NeuroOne Medical Technolohies Corp.
The 510(k) summary of the predicate device is provided as K222404.pdf
This predicate has not been subject to a design-related recall.

Predicate Device: DIXI Medical Microdeep Depth Electrode
Predicate 510(K) number: K170959
Manufacture: DIXI Medical.
The 510(k) summary of the predicate device is provided as K170959. pdf

Predicate Device: Depth Electrodes
Predicate 510(K) number: K163355
Manufacture: Ad-tech Medical Instrument Corporation
The 510(k) summary of the predicate device is provided as K163355.pdf

No reference devices were used in this submission.

IV.Description of Device

The Depth Electrode consists of the Depth Electrode (electrode) and accessories. The accessories consists of Connection cable and Guidance screw.The Depth Electrodes are provided sterile after EO sterilization and are single use only.

The electrodes are slender, cylindrical tubes inserted into the brain. The electrodes have conductive contacts at the distal end to monitor the brain's electrical signals or deliver electrical stimulation.

The electrode is a 0.8 mm diameter Polyurethane electrode with platinum-iridium alloy contacts and are available in varying numbers of contacts: 8 to 1 6 contacts, with an exploration length (recording depth) from 26.5 to 63.0 mm. The longitudinal width of each contact is 2.0 mm, and are spaced 1.5 mm apart (distance between contact groups is 10mm).

The Guidance screws are secured in the skull to provide an access point while stabilizing the electrode. It consists of a tube through which the electrode can pass. The proximal end is threaded, allowing the surgeon to screw it into the patient's skull via an appropriately sized burr hole. The distal end is threaded to accept the Sealing Cap of electrodes.

Guidance screws are available in 20 mm, 25 mm, 30 mm, and 35 mm lengths, and can only be used by inserting through a small 2.1mm burr hole drilled in the skull. Guidance screws should be used only when depth electrodes are warranted.

The Connection cables are used for the transmission of electrical signals that connects to EEG monitoring equipment. When performing EEG monitoring, the connection cable of each model shall be used in conjunction with the electrode of the corresponding channel.

The Depth Electrode is temporarily placed (less than 30 days) at the subsurface level of the brain. The system is designed to be used in stereoelectroencephalography (sEEG) procedures.

V.Indication for use

The Depth Electrode is intended for temporary (less than 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 indications of Use statement for the Depth Electrode is identical to the predicate device.

VI.Comparison summary

The following table compares the Subject Device to the predicate device with respect to indications for use, and technological characteristics, forming the basis for the determination of substantial equivalence. The subject device does not raise any new question of safety or effectiveness as compared to the predicate device.

Device Classification Comparison					
	Subject device	**Predicate Device K222404**	**Predicate Device K170959**	**Predicate Device K163355**	**Comparison**
Trade name	Depth Electrode	Evo@sEEG System	DIXI Medical Microdeep Depth Electrode	Depth Electrodes	N/A
Manufacturer	BEIJING SINOVATION MEDICAL TECHNOLOGY CO.,LTD.	NeuroOne Medical Technologies Corp.	DIXI Medical	Ad-tech Medical Instrument Corporation	N/A
Device	882.1330	882.1330	882.1330	882.1330	Identical

Regulation Number:					
Device/Regulation Name:	Electrode, Depth	Electrode, Depth	Electrode, Depth	Electrode, Depth	Identical
Regulation Description/Common name:	Depth electrode	Depth electrode	Electrode, Depth	Electrode, Depth	Identical
Product Code:	GZL	GZL	GZL	GZL	Identical
Device Class/Regulation Classification:	Class II	Class II	Class II	Class II	Identical
Intended Use/Indication for Use Comparison					
Intended Use:	The device is an electrode used for temporary stimulation of,or recording electrical signals at, subsurface levels of the brain.	The device is an electrode used for temporary stimulation of,or recording electrical signals at, subsurface levels of the brain.	A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.	The device 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	Identical
Indication for Use	The device is intended for temporary (less than 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 device is intended for temporary (less than 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 device is intended for temporary (less than 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 device is intended for temporary (less than 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.	Identical
Electrode Technological and Performance Characteristics Comparison					
Electrode Point	0.8 mm	0.8 mm	0.8 mm	0.86-1.96 mm	Identical

Diameter					
Electrode Material	Polyurethane	Polyamide	/	/	Different
Number of Contacts	8-16	5-16	5-18	Up to 16	Minor different
Contact Height/Length	2 mm	2 mm	2 mm	/	Same
Contact spacing	1.5mm	1.5-3.2 mm	1.5-11 mm	/	Minor different
Contact Material	platinum-iridium	Platinum	platinum-iridium	Platinum	Identical
Exploration Length (Recording Depth)	26.5-63 mm	16-80 mm	16-80.5 mm		Minor different
Sterile	EO sterilization	EO sterilization	EO sterilization	EO sterilization	Same
Single-Use	yes	yes	yes	Yes	Same
Environment of Use	Intraoperative and Neurological monitoring locations at subsurface levels of the brain	Intraoperative and Neurological monitoring locations at subsurface levels of the brain	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological	Identical
Duration of Use	Less than 30 days	Less than 30 days	Less than 30 days	Less than 30 days	Same
Maximum Stimulation Charge Density	≤ 30 μC/cm^2	/	≤ 30 μC/cm^2	≤ 30 μC/cm^2	Identical
Where used	Neurosurgical operating room	Neurosurgical operating room	/	/	Identical
Principles of Operation	Depth electrode are temporarily placed at subsurface levels of the brain to record, monitor, and stimulate electrical signals	Depth electrode are temporarily placed at subsurface levels of the brain to record, monitor, and stimulate electrical signals	Depth electrodes are temporarily placed at subsurface levels of the brain to record, monitor, and stimulate electrical signals	/	Identical
Guidance Screw Technological and Performance Characteristics Comparison					
Depth Electrode Diameter	0.8 mm	0.8 mm	0.8 mm	/	Same

Compatibility					
Material(s)	Titanium alloys	Titanium	Titanium alloys	/	Same as K170959
Lengths Offered	20-35 mm	20-35 mm	15-35 mm	/	Same as K222404
Guidance Screw ID	0.9 mm	0.9 mm	0.8 mm	/	Same as K222404
Single-Use	yes	yes	yes	/	same
Sterile	EO sterilization	EO sterilization	EO sterilization	/	same
Environment of Use	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations	/	same
Duration of Use	Less than 30 days	Less than 30 days	Less than 30 days	/	same
Principles of Operation	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	/	Identical

VII. Performance Data

The Depth Electrode has the identical intended use and similar technological characteristics as the predicate, the minor different technological characteristics are Electrode Material, Number of Contacts, Contact Material, Recording Depth of Depth Electrode and Material(s) of Guidance Screw.

Performance testing was conducted to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate device.

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

Test/Standard	**Test Method Summary**	**Result**
Biocompatibility Evaluation [a]Depth Electrode (Tissue/bone, brain and cerebrospinal fluid contact, >24h to 30 days) [b]Sliding Seal Tube and Sealing Cap (Indirect Tissue/bone contact, >24h to 30 days) [c]Guidance Screw (Tissue/bone and cerebrospinal fluid contact, >24h to 30 days)		
[a,b,c]Cytotoxicity ISO 10993-5	MEM Elution using L-929 Cells (GLP)	Pass - Non-cytotoxic
[a,b,c]Irritation ISO 10993-23	Intracutaneous Irritation test (GLP)	Pass - Non-irritant
[a,b,c]Skin sensitization ISO 10993-10	Guinea pig maximization sensitization test (GLP)	Pass - Non-sensitizing
[a,b,c]Pyrogenicity USP<151> ISO	Rabbit material-mediated	Pass - Non-Pyrogenic

10993-11	pyrogenicity test (GLP)	
[a,b,c]Acute systemic toxicity ISO 10993-11	Acute systemic toxicity effects in mice (GLP)	Pass - Non-toxic
[a,b,c]Subacute/Subchronic toxicity ISO 10993-11	Rat IV and IP injection study (GLP) Chemical characterization study with toxicological risk assessment per ISO 10993-17 and ISO 10993-18	Pass - Non-toxic
[c]Subcutaneous Implantation ISO 10993-6	1 week and 30 day Subcutaneous test in Rabbits (GLP)	Pass - Minimal or no reaction
[c]Bone Implantation ISO 10993-6	1 week and 30 day bone implantation in Rabbits (GLP)	Pass - Minimal or no reaction
[a,c]Neurotoxicity	Brain Implantation Study - 1 week and 30 day Brain implantation in Rats (GLP) Paper-based risk assessment of materials and manufacturing In vitro Cytotoxicity Test using neuronal cell model - The activity of differentiated PC-12 Cells and morphology of undifferentiated PC-12 Cells	Pass Acceptable Pass
[a,b,c]Indirect hemolysis ASTM F756-17	Hemolytic test using rabbit blood (GLP)	Pass - Non-hemolytic
[a,b,c]Genotoxicity ISO 10993-3	Bacterial reverse mutation – AMES Assay (GLP)	Pass - Non-mutagenic
	In Vitro mouse lymphoma assay (GLP)	Pass - non-mutagenic, non-clastogenic
Other types of test /verification are as follows:		
Test	**Standards/summary**	**Result**
bench test	Verify the mechanical, electrical and functional of the device	Pass
Electrical safety	IEC 60601-1	Pass
EMC	IEC 60601-1-2	Pass
shelf life	ASTM F1980	Pass
transit testing	ASTM D4169	Pass
EO Sterilization validation	ISO 11135-1	Pass

EO, ECH residue	ISO 10993-7	Pass
Bacterial Endotoxin validation	usp<161>	Pass
Cleaning validation	ISO 19227	Pass

VIII.Conclusion

The Depth Electrode has the identical intended use and similar technological characteristics as the predicate device, the minor different technological characteristics are Electrode Material, Number of Contacts, Contact Material, Exploration Length of Depth Electrode and the Material(s) of Guidance Screw. Performance testing was conducted to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate device. The Depth Electrode has undergone bench test, electrical, biocompatibility, packaging and sterilization testing to demonstrate the differences in the sizes and materials do not raise questions of safety or effectiveness.