September 1, 2021

NeuroOne Medical Technologies Corp.
% Joseph Ostendorf
Manager and Principal Consultant
Ostendorf Consulting, LLC
23879 Blue Spruce Road
Sauk Centre, Minnesota 56378

Re: K211367
Trade/Device Name: Evo sEEG System
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: July 30, 2021
Received: August 2, 2021

Dear Joseph Ostendorf:

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)*
K211367

Device Name
Evo sEEG System

Indications for Use *(Describe)*
The Evo sEEG System is intended for temporary (less than 24 hours) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:	K211367
Date Prepared:	September 01, 2021
Applicant:	NeuroOne Medical Technologies Corp. 7599 Anagram Drive Eden Prairie, MN 55344 Phone: (952) 426-1383 E-mail: info@n1mtc.com
Contact Person:	Joseph Ostendorf Regulatory Affairs Consultant 7599 Anagram Drive Eden Prairie, MN 55344

SUBJECT DEVICE

Trade/Device Name:	Evo sEEG System
Device Regulation Number:	21 CFR§882.1330
Device / Regulation Name:	Electrode, Depth
Regulation Description / Common Name:	Depth electrode
Product Code:	GZL
Device Class / Regulation Classification:	Class II

DEVICE DESCRIPTION (For the Device Subject to this 510(k) Premarket Notification)

The NeuroOne Evo sEEG System is comprised of the Evo sEEG Electrodes (which includes Anchor Bolt Cap and Stylet) accompanying Cable Assemblies, and the Evo Anchor Bolts. The Evo sEEG System components are provided sterile and are single use only. The Evo sEEG Electrodes are temporarily placed (less than 24 hours) at the subsurface level of the brain. The system is designed to be used in stereoelectroencephalography (sEEG) procedures.

The sEEG electrodes, by way of the accompanying cable assemblies, are connected to recording, monitoring, or stimulation/response instrumentation currently commercially available for use with other sEEG electrodes, including the predicate device.

The sEEG electrodes are a 0.8 mm diameter polyimide electrode with platinum contacts and are available in varying numbers of contacts: 5 to 16 contacts, with an exploration length (recording depth) from 16 to 80 mm. The contact height is 2.0 mm and spacing is 1.5-3.2 mm apart.

The Evo Anchor Bolts are available in 20 mm, 25 mm, 30 mm, and 35 mm lengths, can only be used and placed through a small 2.1 mm burr hole drilled in the skull, and should be used only when sEEG depth electrodes are warranted.

INDICATIONS FOR USE (For the Device Subject to this 510(k) Premarket Notification)

The Evo sEEG System is intended for temporary (less than 24 hours) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain.

DEVICE CLASSIFICATION, INTENDED USE/INDICATIONS FOR USE, AND TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS COMPARISONS

The following tables provide a side-by-side comparison of the Evo sEEG System to the predicate device to support this pre-market notification.

Device Classification Comparison		
	Subject Device K211367	**Predicate Device K170959**
Trade/Device Name:	Evo sEEG System	DIXI Medical Microdeep Depth Electrode
Device Regulation Number:	21 CFR§882.1330	21 CFR§882.1330
Device / Regulation Name:	Electrode, Depth	Electrode, Depth
Regulation Description / Common Name:	Depth electrode	Depth electrode
Product Code:	GZL	GZL
Device Class / Regulation Classification:	Class II	Class II

Intended Use/Indications for Use Comparison		
	Subject Device K211367	**Predicate Device K170959**
Intended Use	A depth electrode 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.
Indications for Use	The Evo sEEG System is intended for temporary (less than 24 hours) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain.	The DIXI Medical Microdeep Depth Electrodes are intended for temporary (<30 day) use with recording, monitoring and stimulation equipment for the recording, monitoring and stimulation of electrical signals at the subsurface level of the brain.

Electrode Technological and Performance Characteristics Comparison		
	Subject Device K211367	**Predicate Device K170959**
Manufacturer	NeuroOne Medical Technologies Corp.	DIXI Medical
Electrode Diameter	0.8 mm	0.8 mm
Electrode Material	Polyimide	Polyamide
Number of Contacts	5 – 16	5 – 18
Contact Height/Length	2 mm	2 mm
Contact Spacing	1.5 – 3.2 mm	1.5 - 11 mm
Contact Material(s)	Platinum	Platinum/iridium
Exploration Length (Recording Depth)	16 – 80 mm	16 – 80.5 mm
Single patient use, Disposable	Yes	Yes
Provided Sterile	Yes	Yes
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
Duration of Use	Less than 24 hours	Less than 30 days
Principles of Operation	Depth electrodes 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

Anchor Bolt Technological and Performance Characteristics Comparison		
	Subject Device K211367	**Predicate Device K170959**
Manufacturer	NeuroOne Medical Technologies Corp.	DIXI Medical
Depth Electrode Diameter Compatibility	0.8 mm	0.8 mm
Material(s)	Titanium	Titanium
Lengths Offered	20 – 35 mm	15 - 35 mm
Anchor Bolt ID	0.9 mm	0.9 mm
Single patient use, Disposable	Yes	Yes
Provided Sterile	Yes	Yes
Environment of Use	Intraoperative and Neurological monitoring locations	Intraoperative and Neurological monitoring locations
Duration of Use	Less than 24 hours	Less than 30 days
Principles of Operation	Threaded into a pre-drilled hole in the skull.	Threaded into a pre-drilled hole in the skull.

SIMILIARITIES AND DIFFERENCES TO THE PREDICATE (For the Device Subject to this 510(k) Premarket Notification)

There are similarities and differences between the subject and predicate devices. The NeuroOne Evo sEEG System and the DIXI Medical Microdeep Depth Electrode devices have the same Device Regulation Numbers, Device / Regulation Names, Regulation Description / Common Names, Product Codes, and Device Class / Regulation Classifications.

Both devices have identical Intended Uses and similar Indications for Use.

The devices further possess the same Electrode Diameters. The NeuroOne Evo sEEG System has a similar material as the DIXI Medical Microdeep Depth Electrode as both utilize polymer materials for the electrode body and for their insulative properties. The NeuroOne Evo sEEG System has a similar Number of Contacts and is within the range of contacts offered for the DIXI Medical Microdeep Depth Electrodes. Both devices share the same electrode Contact Height/Length. The NeuroOne Evo sEEG System has similar Contact Spacing and utilizes variable contact spacing across the device size configurations whereas the DIXI Medical Microdeep Depth Electrodes utilizes the same Contact Spacing across all device size configurations. The devices are similar in both utilizing platinum contacts, although the DIXI Medical Microdeep Depth Electrodes have platinum/iridium contacts. The NeuroOne Evo sEEG System has a similar Exploration Length (Recording Depth) and is within the range of Exploration Length (Recording Depth) offered for the DIXI Medical Microdeep Depth Electrodes. Both devices are Single Patient Use, Disposable devices, which are provided Sterile. They both are used in the same Environment of Use and share similar Durations of Use. And finally, they both have the very same principles of operation.

The NeuroOne Evo Anchor Bolts and the DIXI Medical Microdeep Depth Electrode anchor bolts have the same Depth Electrode Diameter Compatibility and Material(s). The anchor bolts Lengths Offered with the NeuroOne Evo Anchor Bolts are similar to the DIXI Medical Microdeep Depth Electrode anchor bolts and are within the range offered by the DIXI Medical Microdeep Depth Electrode anchor bolts. The Evo Anchor Bolts have the same Anchor Bolt IDs as the DIXI Medical Microdeep Depth Electrode anchor bolts. Both devices are Single Patient use, Disposable devices, which are provided Sterile. They both are used in the same Environment of Use and share similar Durations of Use. And finally, they both have the very same Principles of Operation.

Performance testing was conducted to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate device. A comparison was made against the predicate where data was available. The Evo sEEG System has undergone bench, electrical, biocompatibility, packaging, and sterilization testing to demonstrate the differences in the sizes and materials do not raise questions of safety or efficacy.

SUMMARY OF PERFORMANCE TESTING AND STANDARDS

Performance testing was conducted to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate device. A comparison was made against the predicate where data was available. The Evo sEEG System has undergone non-clinical performance, biocompatibility, sterility, shelf-life, and packaging testing to demonstrate that the results do not raise questions of safety or efficacy.

Non-Clinical Performance Tests		
Test	**Test Method Summary**	**Results and Conclusions**
Dimensional	Electrode Outer Diameter	Pass – All samples passed the acceptance criteria
	Electrode Working Length	Pass – All samples passed the acceptance criteria
	Electrode Recording Depth	Pass – All samples passed the acceptance criteria
	Electrode Contact Spacing	Pass – All samples passed the acceptance criteria
	Electrode Contact Size	Pass – All samples passed the acceptance criteria
	Electrode Tail	Pass – All samples passed the acceptance criteria
	Anchor Bolt Compatibility – Outer Diameter	Pass – All samples passed the acceptance criteria
Mechanical Performance - Implantation	Anchor Bolt Placement Torque	Pass – All samples passed the acceptance criteria
	Anchor Bolt Removal Torque	Pass – All samples passed the acceptance criteria
	Electrode Depth Setting	Pass – All samples passed the acceptance criteria
	Electrode Depth Setting – Sliding Force	Pass – All samples passed the acceptance criteria
	Electrode Through Anchor Bolt	Pass – All samples passed the acceptance criteria
	Electrode Stylet Removal	Pass – All samples passed the acceptance criteria
	Anchor Bolt Cap Torque	Pass – All samples passed the acceptance criteria
	Anchor Bolt Cap Torque Movement	Pass – All samples passed the acceptance criteria
	Electrode Migration	Pass – All samples passed the acceptance criteria
Electrochemical Performance	Impedance	Pass – All samples passed the acceptance criteria
	Reliability	Pass – All samples passed the acceptance criteria
	Stimulation	Pass – All samples passed the acceptance criteria
	Detection	Pass – All samples passed the acceptance criteria
	Kink Resistance	Pass – All samples passed the acceptance criteria

Mechanical Performance – Monitoring	Electrode Rigidity	Pass – All samples passed the acceptance criteria
	Anchor Bolt Cap Torque	Pass – All samples passed the acceptance criteria
	Anchor Bolt Cap Sealing	Pass – All samples passed the acceptance criteria
	Electrode Flexibility	Pass – All samples passed the acceptance criteria
Mechanical Integrity	Anchor Bolt Compatibility – Torque	Pass – All samples passed the acceptance criteria
	Anchor Bolt Retention	Pass – All samples passed the acceptance criteria
	Electrode Integrity	Pass – All samples passed the acceptance criteria
	Anchor Bolt Cap Integrity	Pass – All samples passed the acceptance criteria
	Guiding Stylet Integrity	Pass – All samples passed the acceptance criteria
Electrical Safety	Product shall meet the applicable requirements of the IEC 60601-1 standard.	Pass – All samples passed the acceptance criteria
Packaging	The packaged device and labeling shall withstand the conditions of ISTA 3A and ASTM D-4169; DC13; AL1 without loss of function, sterility, or legibility.	Pass – All samples passed the acceptance criteria
Shelf-Life	The packaged device and labeling shall withstand simulated storage conditions without loss of function, sterility, or legibility.	Pass – All samples passed the acceptance criteria
Sterilization	The sterilization process shall be validated to demonstrate a minimum of SAL of 10^{-6} for the product using Ethylene Oxide.	Pass – All samples passed the acceptance criteria

Biocompatibility		
Test	**Test Summary**	**Conclusions**
Cytotoxicity	ISO MEM Elution Using Mouse Fibroblast Cells - 72 Hour Extraction (GLP)	Pass – Non-cytotoxic
Sensitization	ISO Guinea Pig Maximization Sensitization (GLP - 2 Extracts)	Pass – Did not elicit a sensitization response
Irritation	ISO Intracutaneous Irritation (GLP - 2 Extracts)	Pass – The requirements of the ISO Intracutaneous Reactivity Test have been met
Acute Systemic Toxicity	ISO Acute Systemic Toxicity (GLP - 2 Extracts)	Pass – The ISO Acute Systemic Injection Test have been met
Material Mediated Pyrogenicity	ISO Materials Mediated Rabbit Pyrogen (GLP)	Pass – Non-pyrogenetic

Implantation	Provide general information on the health hazards likely to arise from continuous exposure of the device for local tissue/bone response to implantation sites in both an ovine brain implantation study (including assessment for neurotoxicity) and rabbit tibia study (Evo sEEG anchor bolt only).	Pass – Minimal or no reaction
Hemolysis	ASTM Hemolysis - Direct Contact and Extract Method (GLP)	Pass – Non-hemolytic

Simulated Use and Implantation Accuracy Study
Results and Conclusions
A human cadaver study was conducted by NeuroOne Medical Technologies Corp. with the purpose of demonstrating the simulated use of the Evo sEEG System, and its implantation accuracy, when implanted according to its Instructions For Use (IFU). The implantation accuracy of the Evo sEEG System was compared to the implantation accuracy of the predicate DIXI Medical Microdeep Depth Electrode (K170959). The results demonstrated no significant difference between the implantation accuracy of the subject and predicate devices and therefore these devices are substantially equivalent when evaluating implantation accuracy.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Intended Use, Fundamental Scientific Technology, and Principles of Operation for the Evo sEEG System are the same as those described for the predicate device. The Evo sEEG System does not raise new questions regarding safety and effectiveness when compared to the predicate device and has been determined by NeuroOne Medical Technologies Corp. to be substantially equivalent.

In summary, the Evo sEEG System has the following similarities to the predicate device, which has previously received 510(k) clearance:

- Has the ***same*** device classification
- Has the ***same*** intended use
- Has the ***similar*** indications for use
- Has the ***same*** environment of use
- Uses ***similar*** technological characteristics
- Uses the ***same*** principles of operation
- Uses the ***same*** sterilization methodology
- ***Is*** biocompatible for its intended use

Therefore, the conclusions drawn from the non-clinical and clinical tests (biocompatibility) demonstrate the device is as safe, as effective, and performs as well as the legally marketed predicate device, per 21 CFR 807.92(b)(3). The Evo sEEG System is substantially equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS

Through the thorough comparison of technological and performance characteristics, the subject device is determined to be substantially equivalent to the predicate device.