NeuroOne Medical Technologies Corp.
Debra Kridner
Regulatory Affairs Consultant
7599 Anagram Drive
Eden Prairie, MN 55344

October 20, 2022

Re: K222404
Trade/Device Name: Evo® sEEG System
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: August 8, 2022
Received: August 9, 2022

Dear Debra Kridner:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222404

Device Name
Evo® sEEG System

Indications for Use *(Describe)*
The Evo® sEEG System 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: K222404

Date Prepared: October 18, 2022

Applicant: NeuroOne Medical Technologies Corp.
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Phone: (952) 426-1383
E-mail: info@n1mtc.com

Contact Person: Debra Kridner
Regulatory Affairs Consultant
7599 Anagram Drive
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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 and Anchor Bolts are temporarily placed (less than 30 days) 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 0.8mm 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 80mm. The contact height is 2.0mm and spacing is 1.5-3.2mm apart.

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

INDICATIONS FOR USE

The Evo® sEEG System 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.

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

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

Device Classification Comparison			
	Subject Device K222404	**Predicate Device K211367**	**Comparison**
Trade/Device Name:	Evo® sEEG System	Evo® sEEG System	Identical
Device Regulation Number:	21 CFR § 882.1330	21 CFR § 882.1330	Identical
Device / Regulation Name:	Electrode, Depth	Electrode, Depth	Identical
Regulation Description / Common Name:	Depth electrode	Depth electrode	Identical
Product Code:	GZL	GZL	Identical
Device Class / Regulation Classification:	Class II	Class II	Identical

Intended Use/Indications for Use Comparison			
	Subject Device 222404	**Predicate Device K211367**	**Comparison**
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.	Identical
Indications for Use	The Evo® sEEG System 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 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.	**Substantially Equivalent** – Modified duration of use, for the subject device, which is prolonged duration of use (less than 30 days) whereas the predicate device was cleared with limited duration of use (less than 24 hours).

SIMILIARITIES AND DIFFERENCES TO THE PREDICATE

There is only one difference between the subject and the predicate device. The subject device has the same Indications for Use with the **only** modification being the extend duration of use. The subject device is indicated for prolonged duration of use (less than 30 days) whereas the predicate device was cleared with limited duration of use (less than 24 hours). With the exception of the indicated duration of use, the subject and predicate device are identical.

SUMMARY OF PERFORMANCE TESTING AND STANDARDS

Performance evaluations were conducted to address the proposed extended duration of use in accordance with ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process and ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for Systemic Toxicity process to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate device

The Evo® sEEG System has undergone additional biocompatibility testing to support a prolonged duration of use (less than 30

days) and demonstrated that the results of the extension in the duration of use of the device do not raise new questions of safety or efficacy. Biocompatibility testing was conducted to evaluate and characterize the performance of the device to support a determination of substantial equivalence to the predicate device where changes were made, as part of this 510(k).

Test/Standard	Tested Components	Summary	Conclusion
Implanted[a] and Skin-contacting[b] Components:			
Cytotoxicity ISO 10993-5: 2009	Implanted[a] Skin-contacting[b]	ISO MEM Elution Using Mouse Fibroblast Cells - 72 Hour Extraction (GLP)	Pass – Non-cytotoxic
Sensitization ISO 10993-10: 2010	Implanted[a]	ISO Guinea Pig Maximization Sensitization (GLP - 2 Extracts)	Pass – Non-sensitizer
	Skin-contacting[b]	ISO Buehler Repeated Patch Test (GLP)	Pass – Non-sensitizer
Irritation ISO 10993-10: 2010	Implanted[a]	ISO Intracutaneous Irritation Test (GLP - 2 Extracts)	Pass – Non-irritant
	Skin-contacting[b]	ISO Primary Irritation Test (GLP)	Pass – Non-irritant
Implanted[a] Components:			
Systemic Toxicity ISO 10993-11: 2017	Implanted[a]	ISO Acute Systemic Injection Test (GLP - 2 Extracts)	Pass – Non-toxic
	Implanted[a]	ISO Materials Mediated Rabbit Pyrogen (GLP)	Pass – Non-pyrogenic
Implantation ISO 10993-6: 2016	Implanted[a]	Chronic (29 Days) GLP Brain Tissue Implantation Study (Sheep)	Pass – Minimal or no reaction
Hemolysis ISO 10993-4: 2017	Implanted[a]	ASTM Hemolysis - Direct Contact and Extract Method (GLP)	Pass – Non-hemolytic
Genotoxicity ISO 10993-3: 2014	Implanted[a]	In Vitro Mouse Lymphoma with Extended Treatment (GLP)	Pass – Non-mutagenic and Non-clastogenic.
	Implanted[a]	ISO Bacterial Mutagenicity Test Ames Assay (GLP)	Pass – Non-mutagenic
Subacute Toxicity ISO 10993-11: 2017	Implanted[a]	Subacute (28 Day) Intraperitoneal Toxicity Study in Rats: Method with 14 Dose Exposure (GLP)	Pass – Considered negative for signs of systemic toxicity
	Implanted[a]	Subchronic (28 Day) Intravenous Toxicity Study in Rats: Method with 28 Dose Exposure (GLP)	Pass – Considered negative for signs of systemic toxicity

[a]**Components tested**: Electrode, Anchor Bolt, Cap with prolonged (>24 hours to 30 days) contact with tissue/bone
[b]**Components tested:** Strain Relief, Lock Band, Stylet Assembly, Electrode Tail, and Electrode Connector with limited (<24 hours) contact with intact skin

Other non-clinical performance tests, including dimensional verification, mechanical testing, electrochemical testing, electrical safety testing, packaging testing, shelf-life testing and sterilization validation, were not needed as the differences in duration of use do not affect these device properties and the results of these non-clinical tests were provided in the predicate submission.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Intended Use, Fundamental Scientific Technology, and Principles of Operation for the Evo® sEEG System, which has biocompatibility testing to support prolonged duration of use are the same as those described for the predicate device. The Evo® sEEG System which has biocompatibility testing to support prolonged duration of use 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 subject device Evo® sEEG System has the following similarities to the predicate device which are relevant to the

conclusion that they are substantially equivalent:

- Has the ***identical*** intended use
- Has ***substantially equivalent*** indications for use (<30 days vs. < 24 hours for predicate)
- Has the ***identical*** technological characteristics
- ***Performance Testing demonstrates it is*** biocompatible for new indication (< 30 days)

Therefore, the conclusions drawn from the additional biocompatibility tests demonstrate the device can be used for less than 30 days, 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 with prolonged duration of use is substantially equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS

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