December 22, 2017

Alpha Omega Engineering Ltd,
Maysana Mousa
QA/RA Manager
Nazareth Industrial Park, Mount Precipice, St.2015
Nazareth, 1612102 IL

Re: K171581
Trade/Device Name: Neuro Omega System
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL, GWF, IKN, GWQ, GYC
Dated: November 13, 2017
Received: November 20, 2017

Dear Ms. Mousa:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2017.12.22 14:03:23 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K171581

Device Name
Neuro Omega System

Indications for Use *(Describe)*
The subject device, the Neuro Omega System incorporated the installed HaGuide software, including the Drive HeadStage unit, is intended to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes. The subject device, the Neuro Omega System incorporated the installed HaGuide software is also intended:
-To monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG).

-To measure, record and display the electrical activity of the patient's brain obtained from two or more electrodes on the head (EEG).

-To measure, display and record the electrical activity of the patient's brain obtained from ECOG strip and grid electrodes.

-To provide stimulation via electrode pairs or a hand held bipolar probe for use in functional brain mapping procedures during treatment of patients with seizure disorder.

The device is intended for intraoperative use by medical personnel. Within hospitals, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

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

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92

Submitter Information

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Device Classification

Proprietary Device Name:	Neuro Omega System
Common name:	lntraoperative neurophysiological recording and stimulating device
Product Code:	GZL
Subsequent Product Code:	GWF, IKN, GWQ, GYC
Classification Name:	Depth Electrode
Subsequent Classification names:	Electroencephalograph, stimulator, electrical, evoked response, electromyograph, diagnostic, cortical electrode
Classification Regulation:	21 CFR §882.1330
Regulatory Class:	II

Identification of Legally Marketed Predicate Devices

Neuro Omega System -	K123796
For cortical recording and stimulation	
Nicolet Cortical Stimulator -	K072964

1. Device Description

The Neuro Omega system is designed for different neurosurgery and neurophysiologic clinical applications including recording from and stimulate brain motor and sensory neurons to accurate navigation of electrodes for neurosurgery target localization in treatment of movement disorders by and to aid in the placement of depth electrodes.
The device is also designed for measuring bioelectric signals produced by muscles and stimulate peripheral nerves to aid in the diagnosis and prognosis of neuromuscular disease (EMG).
The device may also be used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).
The subject device, the Neuro Omega System may also be used to measure, display and record the electrical activity of the patient's brain obtained from ECOG strip and grid electrodes.
The subject device, the Neuro Omega System may also be used to provide stimulation via electrode pairs or a hand held bipolar probe for use in functional brain mapping procedures during treatment of patients with seizure disorder.
The subject device, the Neuro Omega System incorporated the installed **HaGuide** software as a user option tool, which is a real-time software solution designed to accurately detects the Sub Thalamic Nucleus region, its entrance and exit boundaries as well gives the user a stimulation location recommendation.
The HaGuide software robustly detects intra STN detection of Dorso lateral Oscillatory Region (DLOR) and Ventro Medical Non-Oscillatory Region (VMNR) boundary. The tool presents real time graphs of power spectrum density and RMS of each region.

2. Intended Use of Device

The subject device, the Neuro Omega System incorporated the installed **HaGuide** software, including the Drive HeadStage unit, is intended to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes.

The subject device, the Neuro Omega System incorporated the installed **HaGuide** software is also intended:

To monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG).

To measure, record and display the electrical activity of the patient's brain obtained from two or more electrodes on the head (EEG).

To measure, display and record the electrical activity of the patient's brain obtained from ECOG strip and grid electrodes.

To provide stimulation via electrode pairs or a hand held bipolar probe for use in functional brain mapping procedures during treatment of patients with seizure disorder.

The device is intended for intraoperative use by medical personnel. Within hospitals, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

3. Safety & Effectiveness

The Neuro Omega System has been compared to the predicate device, Neuro Omega System (K123796), in terms of intended use, indications for use, components, principles of operation, technological characteristics and safety features.

- **Intended Use Comparison**

#	Comparison parameter	Subject device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device for cortical recording and stimulation: Nicolet Cortical Stimulator	SE comparison discussion
1	**Legally distribution clearance No.**	**Subject device**	**K123796**	**K072964**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	**Cardinal Health, Inc**	
3	Intended use and indications for use.	The subject device, the Neuro Omega System incorporated the installed HaGuide software, including the Drive HeadStage unit, is intended to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes. The subject device, the Neuro Omega System incorporated	The Neuro Omega System, including the NeuroDrive unit, is intended to assist neurosurgeons in the operating room during functional neurosurgery and to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes. The Neuro Omega System is also intended to monitor, record and display the bioelectric signals produced by	The Cortical Stimulator is intended for use in functional brain mapping procedures during treatment of patients with seizure disorder, providing stimulation via electrode pairs or a hand held bipolar probe	Similarity The intended use and indications of the modified Neuro Omega is identical to the intended use and indications of the legally marketed Neuro Omega and the Nicolet Cortical Stimulator predicate Devices. Differences The intended use and indications of the modified

#	Comparison parameter	Subject device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device for cortical recording and stimulation: Nicolet Cortical Stimulator	SE comparison discussion
		the installed HaGuide software is also intended: To monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). To measure, record and display the electrical activity of the patient's brain obtained from two or more electrodes on the head (EEG). To measure, display and record the electrical activity of the patient's brain obtained from ECOG strip and grid electrodes. To provide stimulation via electrode pairs or a hand held bipolar probe for use in functional brain mapping procedures during treatment of patients with seizure disorder. The device is intended for	muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device may also be used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG). The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.		Neuro Omega combines the intended use and indications of the predicate and reference devices.

#	Comparison parameter	Subject device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device for cortical recording and stimulation: Nicolet Cortical Stimulator	SE comparison discussion
		intraoperative use by medical personnel. Within hospitals, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording. The device is intended for intraoperative use by medical personnel. Within hospitals, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.			
4	Device code and regulation	**Product Code:** GZL **Regulation #**: 21CFR882.1330 **Subsequent Product Code**: GWF, IKN, GWQ, GYC **Subsequent Regulation #**: 21CFR882.1870, 21CFR	**Product Code:** GZL **Regulation #**: 21CFR882.1330 **Subsequent Product Code**: GWF, IKN, GWQ **Subsequent Regulation #**: 21CFR882.1870, 21CFR	**Product Code**: GYC **Regulation #**: 21CFR882.1310	<u>Similarity</u> The device code and regulation number of the modified Neuro Omega are identical to the intended use and indications of the legally marketed Neuro

#	Comparison parameter	Subject device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device for cortical recording and stimulation: Nicolet Cortical Stimulator	SE comparison discussion
		890.1375, 21CFR882.1400, 21CFR882.1310	890.1375, 21CFR882.1400		Omega and the Nicolet Cortical Stimulator Predicate Devices. <u>Differences</u> The device code and regulation number of the modified Neuro Omega combines the device code and regulation number of the predicate and reference devices. Additionally, the modified Neuro Omega does not include the ETN device code

- **Performance Comparison**

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
1	**Legally distribution clearance No.**	**Subject device**	**K123796**	**K072964**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	**Cardinal Health, Inc**	
3	Body Areas	Deep brain, cranial surface, intracranial cortex and body	Deep brain, cranial surface and body limbs	Intracranial brain cortex	<u>Similarity</u> Identical for Neuro Omega

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
		limbs			modified and unmodified devices Differences In addition to deep brain, cranial surface and body limbs, the modified Neuro Omega may be used mapping the brain by stimulation of the cortical surface, which is equivalent to both predicate and reference devices.
4	Target population	Adults and children	Adults and children	Adults and children	Similarity Identical. Differences None
5	Users	Neurosurgeon, Neurosurgery staff and professional medical personnel.	Neurosurgeon, Neurosurgery staff and professional medical personnel.	Qualified medical personnel	Similarity Identical for Neuro Omega modified and unmodified devices Differences Subject device is equivalent to primary predicate device, Nicolet Cortical Stimulator can be used by qualified medical personnel
6	Use	Within hospitals, laboratory,	Within hospitals, laboratory,	Within a hospital or	Similarity

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
	environment	clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording	clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording	clinical environment.	Identical. Differences Subject device is equivalent to primary predicate device, Nicolet Cortical Stimulator can be used within a hospital or clinical environment.
7	Usability and Human Factors	ISO 62366, IEC 60601-1-6 and FDA draft guidance UCM259760 June 2011	ISO 62366, IEC 60601-1-6 and FDA draft guidance UCM259760 June 2011	Unknown	Similarity Identical for Neuro Omega modified and unmodified devices Differences None
8	AC Power Supply	100-120 V AC,220-240V AC 50/ 60 Hz	100-120 V AC,220-240V AC 50/ 60 Hz	100-120 V AC,220-240V AC 50/ 60 Hz	Similarity Identical. Differences None
9	Software applications	GUI, Monitoring, display, Audio, signal processing, Recording, Stimulation control, identify number of channels connected.	GUI, Monitoring, display, Audio, signal processing, Recording, Stimulation control, identify number of channels connected.	GUI, display, signal processing and Stimulation control	Similarity Identical. Differences None
10.	Electrical Safety	IEC 60601-1 3rd ED + Risk analysis (ISO 14971)	IEC 60601-1 + Risk analysis (ISO 14971)	IEC 60601-1	Similarity Tested for same or more resent safety standards Differences

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
					None
11	Particular safety	IEC 60601-2-10, IEC 60601-2-26, IEC 60601-2-40 + Risk analysis (ISO 14971)	IEC 60601-2-10, IEC 60601-2-26, IEC 60601-2-40 + Risk analysis (ISO 14971)	IEC 60601-1, IEC 60601-2-26	Similarity Identical. Differences None
12	Electromagnetic Compatibility	IEC 60601-1-2 + Risk analysis (ISO 14971)	IEC 60601-1-2 + Risk analysis (ISO 14971)	IEC 60601-1-2	Similarity Identical. Differences None
13	Sterility and Sterility standards	Sterility of the reusable components is performed by the hospital clinical staff and was validated to comply with the following standards: ISO 17665-1, ST81 and STERRAD	Sterility of the reusable components is performed by the hospital clinical staff and was validated to comply with the following standards: ISO 11135, ISO 10993-7, ST77, ST81, ST67	Not relevant for the ECoG.	Similarity Identical for Neuro Omega modified and unmodified devices Differences For the modified Neuro Omega system only STERRAD sterilization is allowed for HeadStage electronic components, while in the legally cleared device ETO and STERRAD were allowed.
14	Software development standard	ISO 62304	ISO 62304	Not relevant for the ECoG.	Similarity Identical for Neuro Omega modified and unmodified

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
					devices Differences None
15	Electrical Class	I	I	Not relevant for the ECoG.	Similarity Identical for Neuro Omega modified and unmodified devices Differences None
16	Protective Type	BF	BF	BF	Similarity Identical Differences None

- **Technology Comparison**

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
1	**Legally distribution clearance No.**	**Subject device**	**K123796**	**K072964**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	**Cardinal Health, Inc**	
3	Device Components	Main Unit including: Mobile Rack, Power Supply, Isolation Transformer, PC, Monitor, keyboard, mouse, Speakers, I/O analog/ Digital unit and Front End unit. Head Stage components: Head Box, Connection Box. Drive HeadStage System, Remote control handpiece, Head stage cables, and single use electrodes cable.	Main Unit including: Mobile Trolley, Power Supply, Isolation Transformer, Panel PC, Monitor, keyboard, mouse, Speakers and Front End unit. Head Stage components: Head Box module, NeuroDrive System, Remote control handpiece, Head stage recording cable, Head stage cables and single use electrodes cable.	Hand-held unit including; display, power supply and control knob	Similarity Identical for Neuro Omega modified and unmodified devices Differences None
4	Operating System	Windows 7, 64bit	Same	Not relevant for the ECoG HeadBox.	Similarity Identical for Neuro Omega modified and unmodified devices Differences None
5	Computer	Touch screen PC	Industrial PC	Not relevant for the ECoG	Similarity

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
				HeadBox.	Identical for Neuro Omega modified and unmodified devices <u>Differences</u> Due to modern appearance of the modified Neuro Omega, a touch screen PC is used.
6	Trolley Connectors	4 USB ports	4 USB ports	Not relevant	<u>Similarity</u> Identical for Neuro Omega modified and unmodified devices <u>Differences</u> None
7	Main Unit system connectors	•Ethernet ports •1 Remote port •2 Audio out	Same	Not relevant	<u>Similarity</u> Identical for Neuro Omega modified and unmodified devices <u>Differences</u> None
8	Communication	Ethernet protocol	Same	Not relevant	<u>Similarity</u> Identical for Neuro Omega modified and unmodified devices <u>Differences</u> None

#	Comparison parameter	Proposed device: Neuro Omega	Primary Predicate device: Neuro Omega	Reference device: Nicolet Cortical Stimulator	SE comparison discussion
9	Peripherals	Microsoft Wireless keyboard and mouse	Wired keyboard and mouse	Not relevant	Similarity Identical for Neuro Omega modified and unmodified devices Differences Wireless KB and Mouse is more comfortable than wired ones
10	Number of Channels	•Up to 10 MER channels •Up to 112 EEG/EMG/ECOG channels.	Same	Not Applicable	Similarity Identical for Neuro Omega modified and unmodified devices Differences None

Based on the performance results provided in this submission (including test results and clinical evaluation) and the analysis of similarities and differences presented above, Alpha Omega Technologies Ltd. believes that the proposed device is substantially equivalent to the predicate device without raising new safety and/or effectiveness issues.

Rational for Substantial Equivalency

Similarities:

1. The Neuro Omega System and the predicate legally cleared Neuro Omega System (K123796) share the same device code and have the same intended use and indications for use for Depth Electrode Recording and Stimulation, EEG and EMG. Both devices are intended for the same body target organs (Human Brain), same population, same users, same operation environment (operation room) and tested for compliance to the same development control, safety standards and use same technologies i.e. main unit base of standard PC with application software.
   For cortical recording and stimulation, the legally cleared predicate device, Nicolet Cortical Stimulator (K072964) has the same device code and have the same intended use and indications for use.
   The device code and regulation number of the subject device, the modified Neuro Omega, combines the device code and regulation number of the two predicate devices.
   Sterileable components (head stage, Drive HeadStage) that are located inside the sterile operation area are intended for re-sterilization by the hospital staff. Sterileable components where validated for cleaning and sterilization procedures described in the manual.

Differences:

1. In addition to deep brain, cranial surface and body limbs, the modified Neuro Omega may be used mapping the brain by stimulation of the cortical surface, which is equivalent to the predicate device Nicolet Cortical Stimulator (K072964).
2. For the modified Neuro Omega system only STERRAD sterilization is allowed for HeadStage electronic components, while in the legally cleared device ETO and STERRAD were allowed.

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4. **Performance** Tests

For non-clinical performance tests:

Test	Test Method Summary	Results
Software Verification	This verification performed on full system, the subject device (SW & HW) including accessories, and checked that the design output meets the SW design input.	Neuro Omega SW has been tested under a complete SW verification plan traceable to Neuro Omega SRS. All samples passed the acceptance criteria which determines the effectiveness of Neuro Omega System, the subject device, with HaGuide software.
System Verification	This verification performed on full system, the subject device (SW & HW), and checked that the design output meets the system (HW & MECH) design input	Neuro Omega system has been verified under a complete system verification plan traceable to Neuro Omega system design input. All samples passed the acceptance criteria which determines the effectiveness of Neuro Omega System, the subject device, with HaGuide software.
Steam Sterilization Validation	Mechanical accessories of the subject device	Each test article was evaluated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using the biological indicator (BI) overkill method. Geobacillus stearothermophilus, ATCC #7953, was the indicator organism. All test method acceptance criteria were met. In addition to the SAL validation, dry times were validated using full cycle parameters.
STERRAD NX sterilization validation	Electrical accessories of the subject device	Each test article was evaluated to a sterility assurance level (SAL) of $\leq 10^{-6}$ using the biological indicator (BI) overkill method. Geobacillus stearothermophilus, ATCC #7953, was the indicator organism. Results validate the individual test articles for the STERRAD® NX standard cycle.
STERRAD 100NX sterilization validation	Electrical accessories of the subject device	Results from testing validate that the Alpha Omega Engineering, Ltd. Neuro Omega Tray is able to achieve a 10^{-6} SAL in a STERRAD® 100NX Standard sterilization process.

For clinical performance test:

HaGuide Clinical Study:

- **Test Method Summary:**

A Retrospective, Multi-centre, Clinical Validation of HaGuide Software module accuracy in mapping sub-thalamic nucleus (STN) boundaries in Parkinson's disease patients who underwent Deep Brain Stimulation (DBS) procedure

- **Level of evidence:**

Single-arm study with Objective Performance Criteria

- **Location of Study:**

Both in United States and Outside Unitest States

- **Primary Effectivness Endpoint:**

Percent agreement between HaGuide software measurements and expert Neurosurgeon/Electrophysiologist measurements, for STN entry point vs. exit point depth (in mm).

- **Patient Accountability:**

Stage	Investigational Device Arm total	Control Arm Total	Total
Enrollment	81	-	81
Treatment	81	-	81
Primary Effectivness Endpoint Analysis	81	-	81

- **The study met the primary endpoint:**

The reference against which the accuracy of HaGuide mapping was compared is the gold standard being the qualified user (Neurosurgeon/Electrophysiologist) concluding about the location of the entry and exit points of the sub-thalamic nucleus (STN) from the visual and audio recording patterns.

- **Results:**

In total 81 patients were enrolled. In total 105 surgeries, as 213 electrodes were evaluated for percent agreement between HaGuide software measurements and expert Neurosurgeon/Electrophysiologist measurements about the location of the entry and exit points of the sub-thalamic nucleus (STN).

Percent agreement between Haguide and Neurosurgeon/Electrophysiologist expert is 90.34% (95% CI, 85.27, 93.85 %)

Correlation between the HaGuide measurements and expert Neurosurgeon/Electrophysiologist measurements in depth of STN entry site and exit site and was found very strong (coefficient = 0.9492 and 0.9317 respectively and both lower 95% Confidence Limit >0.91).

Bland-Altman analysis of average against the difference between Haguide and expert measurements for the location of STN entry was 0.18 mm (95% CI, -0.9, 1.2 mm) and exit points was -0.15 mm (95% CI, -1.25, 1 mm).

- **No adverse events and complications observed in the study**

5. Substantial Equivalence Statement

Based on the above, it is Alpha Omega's opinion that the proposed modified Neuro Omega System is substantially equivalent in terms of design principles, performance features and of safety & effectiveness to the predicate legally cleared devices referred to in section 3 of this document.