February 27, 2018

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

Re: K172042
Trade/Device Name: NeuroNav System, NeuroSmart System, and NeuroNav Drive
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: December 27, 2017
Received: January 11, 2018

Dear Maysana 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,

Michael J. Hoffmann -S

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)*
K172042

Device Name
NeuroNav System, NeuroSmart System, and NeuroNav Drive

Indications for Use *(Describe)*
The NeuroNav System / NeuroSmart System, incorporated the installed HaGuide software, is intended to be used in assisting 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 electrode.

The NeuroNav Drive is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of depth electrodes.

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

Alpha Omega Engineering Ltd.
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Submission contact person:

Mrs. Maysana Mousa
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Device Classification

Proprietary Device Name:	NeuroNav System, NeuroNav Drive and NeuroSmart System
Common name:	lntraoperative neurophysiological recording and stimulating device
Product Code:	GZL
Subsequent Product Code:	
Classification Name:	Depth Electrode
Classification Regulation:	21 CFR §882.1330
Regulatory Class:	II

Identification of Legally Marketed Predicate Devices

NeuroNav System and NeuroNav Drive device - K071697

1. Device Description

Alpha Omega's NeuroNav System is an accurate electrodes navigation system to aid the neurosurgeon in placement of DBS electrodes. The system is designed to be used in the operating room during neurosurgery.
The NeuroNav Drive system is designed for compatibility with Alpha Omega's Microprobes (NeuroProbes K120098) or with other manufacturers' compatible electrodes, and is compatible with all the existing Stereotactic Frames and Frameless procedures.
NeuroNav system can record signals from the brain cells (Micro-Electrode Recording – MER) or stimulate the brain target zone during movement disorders neurosurgery procedure.

In addition, the NeuroNav system is planned to include additional sub model, will be traded as "NeuroSmart", this sub model is identical to the NeuroNav system, the subject device, and incorporated the installed HaGuide software, will be elaborated hereunder.

The installed HaGuide software is 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.

2. Intended Use of Device

The NeuroNav system / NeuroSmart System, incorporated the installed **HaGuide** software, is intended to be used in assisting 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 electrode.

The NeuroNav Drive is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of depth electrodes.

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3. Safety & Effectiveness

The NeuroNav system has been compared to the predicate device, NeuroNav System and NeuroNav device (K071697), in terms of intended use, indications for use, components, principles of operation, technological characteristics and safety features.

- **Intended Use Comparison**

#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
1	**Legally distribution clearance No.**	**Subject device**	**K071697**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	
3	Intended use and indications for use.	NeuroNav System Alpha Omega's NeuroNav system, including the NeuroNav Drive, is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, and to record	NeuroNav System Alpha Omega's NeuroNav system, including the NeuroNav Drive, is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, and to record	Similarities: Same intended use and indications Differences: None

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#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
		from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrode. NeuroNav Drive Alpha Omega NeuroNav Drive is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of depth electrodes.	from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrode. NeuroNav Drive Alpha Omega NeuroNav Drive is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of depth electrodes.	
4	Device code and regulation	**Product Code:** GZL **Regulation #**: 21CFR882.1330	**Product Code:** GZL **Regulation #**: 21CFR882.1330	Similarities: Same product code and regulation Differences: None

- **Performance Comparison**

#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
1	**Legally**	**Subject device**	**K071697**	

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#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
	distribution clearance No.			
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	
3	Target Area	Deep Brain	Deep Brain	Similarities: Same target body target area Differences: None
4	Target population	Adults and children	Adults and children	Similarities: Same target population Differences: None
5	Users	Neurosurgeon and Neurosurgery staff	Neurosurgeon and Neurosurgery staff	Similarities: Same users Differences: None
4	Use environment	Operating Room	Operating Room	Similarities: Same use environment Differences:

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#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
				None
6	Usability and Human Factors	ISO 62366, IEC 60601-1-6 and FDA guidance # 1497 - Incorporating Human Factors in Risk Management dated July 18 2000.	ISO 60601-1-6 and FDA guidance # 1497 - Incorporating Human Factors in Risk Management dated July 18 2000.	Similarities: Conformity to same or newer Human Factors standards Differences: The modified device usability design complies to a newer medical device usability standard (ISO 62366)
7	AC Power Supply	100 - 240V AC 50/ 60 Hz	100-120 V AC,220-240V AC 50/ 60 Hz	Similarities: Same AC Power input Differences: None
8	Software applications	GUI, Monitoring, display, Audio, signal processing, Recording, Stimulation	GUI, Monitoring, display, Recording, Stimulation	Similarities: Same application controlled by the device's software Differences: New and improved applications implemented by the software. The differences do not raise concerns in safety and effectiveness.

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#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
9.	Electrical Safety	IEC 60601-, 3rd Ed. + Risk analysis (ISO 14971)	IEC 60601-1 + Risk analysis (ISO 14971)	Similarities: Conformity to the same or newer safety standard Differences: The modified device was tested for compliance to a newer (3rd edition) medical device safety standard
10.	Particular safety	Risk analysis (ISO 14971)	Risk analysis (ISO 14971)	Similarities: Risk assessment performed according to the same standard Differences: Non
11	Electromagnetic Compatibility	IEC 60601-1-2, 3rd Ed. + Risk analysis (ISO 14971)	IEC 60601-1-2 + Risk analysis (ISO 14971)	Similarities: Conformity to the same or newer EMC standard Differences: The modified device was tested for compliance to a newer (3rd edition) medical device EMC standard
12	Sterility and Sterilization standards	Sterility of the sterileable	Sterility of the sterileable	Similarities:

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#	Comparison parameter	Subject device: Modified NeuroNav System and NeuroNav Drive	Predicate device: NeuroNav System and NeuroNav Drive	Substantial Equivalent discussion
		components is performed by the hospital clinical staff and was validated to comply with the following standards: ISO **17665-1**, ST77	components is performed by the hospital clinical staff and was validated to comply with the following standards: **ISO 17665-1,** ISO 11135, ISO 10993-7, ST77	Conformity to the same or newer sterility validation standards <u>Differences:</u> The modified device head-stage electronic components were validated for compliance with different types of STERRAD sterilization processes instead of ETO sterilization process that is not used for electronic components sterilization.
13	Software development standard	ISO 62304	ISO 60601-1-4	<u>Similarities:</u> Conformity to the same or newer medical device software standard <u>Differences:</u> The modified device software development process complies to a newer medical device life cycle software development standard (ISO 62304)

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Based on the performance results provided in this submission (including test results) 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

The proposed modified NeuroNav system and NeuroNav Drive has been compared to the predicate NeuroNav system and NeuroNav Drive in terms of intended use, indications for use, components, principles of operation, technological characteristics and safety features.
Based on the analysis results provided in this submission, including test results and bench performance tests and the analysis of similarities and differences discussed, Alpha Omega Engineering Ltd. believes that the proposed device is substantial equivalent to the predicate device without raising new safety and/or effectiveness issues.

Non Clinical and Clinical validation data

Verification and validation bench tests were performed, to demonstrate the safety and effectiveness of the proposed NeuroNav System.
The purposes of the design verification & validation processes were to verify the Device specifications and to verify the proper function of all device components and options.

After comparing the predicates device to the subject device, results show that with the above intended use, the device is equivalent in safety and effectiveness.

Therefore, the subject of this 510(k) notification, the NeuroNav system, did not require clinical studies to support safety and effectiveness of the device.

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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.	NeuroNav SW has been tested under a complete SW verification plan traceable to NeuroNav SRS. All samples passed the acceptance criteria which determines the effectiveness of NeuroNav 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	NeuroNav system has been verified under a complete system verification plan traceable to NeuroNav system design input. All samples passed the acceptance criteria which determines the effectiveness of NeuroNav 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	NeuroNav was validated 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 validated the individual test

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		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.

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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 Effectiveness 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).

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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**

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