September 16, 2022

Alpha Omega Engineering Ltd.
Efrat Shamgar
VP Quality & Regulatory Affairs
Hamerkava St.6, Tsiporit Industrial Zone
Nof HaGalil (Nazareth Illit), 1789062
Israel

Re: K220553
Trade/Device Name: Neuro Omega System, NeuroSmart System
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL, GWF, IKN, GWQ, GYC
Dated: August 12, 2022
Received: August 17, 2022

Dear Efrat Shamgar:

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

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)*
K220553

Device Name
Neuro Omega System and NeuroSmart System

Indications for Use *(Describe)*

The Neuro Omega system with the incorporated Navigation Tool software (the improved 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 with the incorporated Navigation Tool 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 a seizure disorder.

The Neuro Omega with the incorporated installed Navigation tool software, is intended for intraoperative use by medical personnel. Within hospitals, laboratories, clinics, or nursing home settings or outside of a medical facility under the direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

The NeuroSmart System with the incorporated Navigation Tool software, is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to record from and stimulate brain motor and sensory neurons and 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.
Registration: 9615126

Submission contact person:

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Date Prepared: September 15, 2022

Device Classification

For Neuro Omega System:

Product Code:	GZL
Subsequent Product Code:	GWF, IKN, GWQ, GYC
CFR section:	21 CFR 882.1330
Subsequent CFR section:	21 CFR 882.1870, 1375, 1400, 1310
Regulation name:	Depth electrode
Subsequent regulation names:	Electroencephalograph, stimulator, electrical, evoked response, electromyography, diagnostic, cortical electrode
Trade Name:	Neuro Omega System
Common Name:	Intraoperative neurophysiological recording and stimulating device
Classification:	Class II

For NeuroSmart System:

Product Code:	GZL
CFR section:	21 CFR 882.1330
Regulation name:	Depth electrode
Trade Name:	NeuroSmart System
Common Name:	Intraoperative neurophysiological recording and stimulating device
Classification:	Class II

1 Identification of Legally Marketed Predicate Devices

- Neuro Omega system (as cleared under K171581)
- NeuroSmart System (as cleared under K172042)

2 Device Description

2.1 Neuro Omega

The Neuro Omega system is designed for different neurosurgery and neurophysiologic clinical applications including recording from and stimulating 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 stimulating 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 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 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 the treatment of patients with a seizure disorder.

The subject device, the Neuro Omega incorporated the installed Navigation Tool software (the improved HaGuide software) is a real-time software incorporated in electrophysiological recording and stimulating systems (like: Neuro Omega and NeuroSmart systems).
The tool is designed to detect the STN region (improved HaGuide Tool as was cleared under K171581 for Neuro Omega & K172042 for NeuroSmart), it detects the entrance and exit boundaries of STN regions. The tool gives the user a stimulation location recommendation. Furthermore, the tool presents real-time graphs of power spectrum density and RMS of STN region.

The Navigation Tool can aid in the placement of a compatible DBS Lead when the lead is connected to the cleared Alpha Omega Disposable Sterile LeadConfirm (K191739) and to the Neuro Omega System. This feature allows the user to record through the implanted lead and based on the recordings show simple spectral measures (PSD) within the frequency bands of interest. Based on the recordings from the lead, and the NeuroProbe MicroElectrode recordings, this feature shows the correlation in frequency band between both these recordings.

When the subject device, the Neuro Omega incorporated the installed Navigation tool is connected to the internet, the relevant intraoperative data collected during DBS surgery can be uploaded to Alpha Omega's cloud by the physician for Neurologist use. This information will assist the Neurologist in programming of the Implantable Pulse Generator (IPG).

2.2 NeuroSmart

Alpha Omega's NeuroSmart system physiological navigation system is accurate, aiding the neurosurgeons during functional neurosurgery for placing Deep Brain Stimulation (DBS) electrodes.

The NeuroSmart system can record signals from the brain cells or stimulate the brain target zone during the operation procedure.

The subject device, the NeuroSmart incorporated the installed Navigation Tool software (the improved HaGuide software) is a real-time software incorporated in electrophysiological recording and stimulating systems (like: Neuro Omega and Neuro Smart systems).

The tool is designed to detect the STN, it detects the entrance and exit boundaries of STN regions. The tool gives the user a stimulation location recommendation. Furthermore, the tool presents real-time graphs of power spectrum density and RMS of each region.

The Navigation Tool can aid in the placement of a compatible DBS Lead when the lead is connected to the cleared Alpha Omega Disposable Sterile LeadConfirm (K191739) and to the NeuroSmart System. This feature will allow the user to record through the implanted lead and based on the recordings show simple spectral measures (PSD) within the frequency bands of interest.

Based on the recordings from the lead and the NeuroProbe MicroElectrode recordings, this feature shows the correlation in frequency band between both these recordings.

When the subject device, the NeuroSmart incorporated the installed Navigation tool is connected to the internet, the relevant intraoperative data collected during DBS surgery can be uploaded to Alpha Omega's cloud by the physician for Neurologist use. This information will assist the Neurologist in programming the Implantable Pulse Generator (IPG).

2.3 Navigation Tool

The Navigation Tool SW can work in two modes:

1. The Navigation Tool can be installed on the Neuro Omega/ NeuroSmart Systems.
2. The Navigation Tool can work as a standalone software, for that purpose it can be installed on external PC to work in off-line mode.

In both modes the safety and effectiveness of the Neuro Omega and NeuroSmart systems are not compromised, as the Navigation Tool software is a non-blocking software (it doesn't affect the system's functionality even in malfunction). The Navigation Tool software can run in both modes without affecting the Neuro Omega system safety and effectiveness, nor its functionality.

The main use of the Navigation tool SW when it runs as a standalone software, is for

visual purpose only, meaning to receive data from the systems and present it in graphs. No changes are made to the retrieved data. Furthermore, the data will be used for verification only for the neurologist prior to fine-tuning the IPG work mode by using the IPG interface (not Alpha Omega's device).

The Navigation Tool provides an option to upload raw data and OR reports to the Alpha Omega server.

- The raw data include the MER .mpx files and the workspace files that were saved during the surgery by the Neuro Omega or NeuroSmart system (if enabled by the user).
- The OR report includes all the HaGuide parameters, OR notes, stimulation assessments, and lead recording.

The Alpha Omega server adheres to industry cybersecurity standards.

The Navigation Tool Software in both its modes, as a standalone software and a software installed on Neuro Omega/NeuroSmart systems, can upload data for storage via secured protocols (FTPS, HTTPS) to Alpha Omega server using the internet connectivity.
Neuro Omega/NeuroSmart software does not upload data to any web server. They are able to connect locally to the Navigation Tool, which is the only channel through which data can be uploaded to Alpha Omega server. The Navigation Tool cannot download or retrieve any data from Alpha Omega server.

3 Intended Use of Device

3.1 Neuro Omega

The Neuro Omega System with the incorporated Navigation Tool software (the improved 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 with the incorporated Navigation Tool 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 a seizure disorder.

The Neuro Omega with the incorporated installed Navigation tool software, is intended for intraoperative use by medical personnel. Within hospitals, laboratories, clinics, or nursing home settings or outside of a medical facility under the direct supervision of a

medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

3.2 NeuroSmart

The NeuroSmart System with the incorporated Navigation Tool software, is intended to be used in assisting neurosurgeons, in the operating room during functional neurosurgery, to record from and stimulate brain motor and sensory neurons and to aid in the placement of depth electrodes.

4 Comparison to Predicate Device

The subject devices, the Neuro Omega/NeuroSmart Systems incorporated the installed Navigation Tool software are substantially equivalent to the predicate devices as claimed in section 1.
The intended use and indications of the proposed Neuro Omega/NeuroSmart Systems are identical to the legally marketed Neuro Omega System (K171581) and to the legally marketed NeuroSmart System (K172042), respectively.

Based on the performance results provided in this submission and the analysis of similarities and differences presented in the Substantial Equivalence Discussion, Alpha Omega Technologies Ltd. believes that the proposed devices are substantially equivalent to the predicate devices without raising new safety and/or effectiveness issues.

4.1 Technology Comparison – Neuro Omega System:

Comparison parameter	**Subject device: Neuro Omega**	**Predicate device: Neuro Omega**	**Substantial Equivalence discussion**
Legally distribution clearance No.	**Subject device; K220553**	**K171581**	

Comparison parameter	**Subject device: Neuro Omega**	**Predicate device: Neuro Omega**	**Substantial Equivalence discussion**
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. Headstage components: HeadBox, Connection Box. Drive Headstage System, Remote control handpiece, Headstage cables, and single-use electrodes cable.	Main Unit including Mobile Rack, Power Supply, Isolation Transformer, PC, Monitor, keyboard, mouse, Speakers, I/O analog/ Digital unit and Front-End unit. Headstage components: HeadBox, Connection Box. Drive Headstage System, Remote control handpiece, Headstage cables, and single-use electrodes cable.	Similarity Identical for the subject device and the predicate Differences None
Operating System	Windows 7, 10, 64bit	Same	Similarity Identical for the subject device and the predicate Differences None
Computer	Touch screen PC	Touch screen PC	Similarity Identical for the subject device and the predicate Differences None
Trolley Connectors	4 USB ports	4 USB ports	Similarity Identical for the subject device and the predicate Differences None
Main Unit system connectors	• Ethernet ports (1 GB) • 1 Remote port (USB) • 2 Audio out (3.5mm stereo)	Same	Similarity Identical for the subject device and the predicate Differences None
Communication	Ethernet protocol	Same	Similarity Identical for the subject device and the predicate Differences None
Peripherals	Wireless keyboard and mouse	Wireless keyboard and mouse	Similarity Identical for the subject device and the predicate. Differences None

Comparison parameter	**Subject device: Neuro Omega**	**Predicate device: Neuro Omega**	**Substantial Equivalence discussion**
Number of Channels	• Up to 10 MER channels (5 Micro and 5 Macro) • Up to 112 EEG/EMG/ECOG channels.	Same	Similarity Identical for the subject device and the predicate Differences None
Software version	Neuro Omega V1.6.2.1 Navigation Tool V4.0.8	Neuro Omega V1.5.1.12	Similarities: Same software modules for supporting the Neuro Omega operation and applications Differences: • Bug fixes The proposed Neuro Omega software supports the connectivity to the Internet Navigation Tool • The differences were taken into consideration during the Risk management phase and all identified hazards were addressed to ensure that the Neuro Omega System remains safe and effective.

Technology Comparison – NeuroSmart System:

Comparison parameter	**Subject device: NeuroSmart**	**Predicate device: NeuroSmart**	**Substantial Equivalence discussion**
Legally distribution clearance No.	**Subject device; K220553**	**K172042**	

Comparison parameter	**Subject device: NeuroSmart**	**Predicate device: NeuroSmart**	**Substantial Equivalence discussion**
Device Components	Main Unit including Mobile Rack, Power Supply, Isolation Transformer, Laptop PC (including Keyboard and Screen), mouse, Speakers and patient isolated unit (Patient Box). Patient area components: Remote control hand-piece and signal cable Headstage components: Drive unit, Headstage recording, and stimulation cable	Main Unit including Mobile Rack, Power Supply, Isolation Transformer, Laptop PC (including Keyboard and Screen), mouse, Speakers and patient isolated unit (Patient Box). Patient area components: Remote control hand-piece and signal cable Headstage components: Drive unit, Headstage recording, and stimulation cable	Similarity Identical for the subject device and the predicate. Differences None
Software version	NeuroSmart V.1.0.10 Navigation Tool V4.0.8	NeuroSmart V-1.0.0	Similarities: Same software modules for supporting the NeuroSmart operation and applications Differences: • The proposed NeuroSmart software supports the connectivity to the Internet • Navigation Tool The differences were taken into consideration during the Risk management phase and all identified hazards were addressed to ensure that the NeuroSmart System remains safe and effective.

5 Summary of non-clinical performance tests:

Test Performed	**Test Method/Applicable Standards**	**Acceptance Criteria**	**Results**
Software /System Verification	Internet Connectivity checkup together with the Neuro Omega/ NeuroSmart	The internet connectivity works according to its	All tests passed the acceptance criteria which determines the

Test Performed	Test Method/Applicable Standards	Acceptance Criteria	Results
*All verification was made according to: • ISO 13485:2016 Medical devices- Quality management systems - Requirements for regulatory purposes • ISO 14971: 2019 Medical devices - Application of risk management to medical devices		intended use without any interrupts to the Neuro Omega/ NeuroSmart Software incorporated with Navigation Tool software (improved HaGuide Software).	effectiveness of Neuro Omega / NeuroSmart System, with Navigation Tool software (improved HaGuide Software).
	Navigation Tool Software GUI functionality	The functionality of the GUI of the Navigation Tool Software works according to its intended use	All tests passed the acceptance criteria
	NRMS and PSD Graphs functionality check-up of the Navigation Tool Software	The functionality of the NRMS and PSD Graphs of the Navigation Tool Software works according to its intended use	All tests passed the acceptance criteria
	Check the functionality of the HaGuide settings in the Navigation Tool Software	The functionality of the HaGuide settings in the Navigation Tool Software works according to its intended use	All tests regarding the Online Lead Correlation feature passed the acceptance criteria
	Recommendation window functionality verification of the improved HaGuide feature in the Navigation Tool Software		All tests passed the acceptance criteria
	Lead Correlation feature functionality in the Navigation Tool Software		All tests regarding the Online Lead Correlation feature passed the acceptance criteria; Offline lead correlation analysis feature observed as a bug. But from clinical point of view this offline feature isn't used during surgeries, it is mostly used in offline analysis.
	General settings functionality in the Navigation Tool Software	The functionality of the General settings in the Navigation Tool Software works according to the its intended use	All tests passed the acceptance criteria

Test Performed	Test Method/Applicable Standards	Acceptance Criteria	Results
Coexistence Testing	Coexistence testing according to "Radio Frequency Wireless Technology in Medical Devices Guidance" FDA Guidance issued August 2013	• The Neuro Omega and NeuroSmart successfully pass the coexistence testing to verify that other devices do not harm the uploading process. • The Neuro Omega and NeuroSmart systems operate as normally when the connection is down.	All tests passed the acceptance criteria
Cybersecurity Penetration Testing	Cybersecurity testing – following "Gray box" approach. The tests were performed based on the industry penetration testing approach derived from the National Institute of Standards and Technology (NIST) Special Publication (SP) ("NIST SP 800-115") – "Technical Guide to information Security Testing and Assessment", the Open Source Security Testing Methodology Manual ("OSSTMM") – authored by the institute for Security and Open Methodologies "ISECON") and the Open Web Application Security Project ("OWASP") testing methodologies.	All security check-ups meets/exceeds the requirements for all well-known and established regulatory and compliance standards	All tests passed the acceptance criteria
PC Suppliers Reports for FCC and EMC	IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic Compatibility and checked that the design output meets the standard requirements, for Neuro Omega supplied PC	The Neuro Omega PC supplier meets IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic Compatibility	The Neuro Omega PC passed with no deviation

Test Performed	Test Method/Applicable Standards	Acceptance Criteria	Results
	FCC Certificate according to the US Code of Federal Regulation (CFR) Title 47, FCC for NeuroSmart PC	Certified Federal Communications Commission (FCC) NeuroSmart PC	Certified Federal Communications Commission (FCC) NeuroSmart PC with no deviation
EMC Reports based on IEC 60601-1-2	IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic Compatibility	The Neuro Omega/ NeuroSmart fulfill the requirements of IEC 60601-1-2:2014 (fourth edition)	All tests passed the acceptance criteria Reports: • Neuro Omega EMC Report E194610.00 Neuro Omega Medical IEC 60601-1-2 2014 • NeuroSmart EMC Report E197560.00

6 Conclusions

Based on the results of the testing above, the modified Neuro Omega/ NeuroSmart Systems are substantially equivalent to the legally cleared predicate devices referred to in section 4 of this document.