March 30, 2025

Alpha Omega Engineering Ltd.
Efrat Shamgar
VP Quality & Regulatory Affairs
Hamerkava St.6, Tsiporit Industrial Zone
P.O. Box 810
Nof HaGalil (Nazareth Illit), 1789062
Israel

Re: K250601
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: February 27, 2025
Received: February 28, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 R. Gupta -S

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)*
K250601

Device Name
Neuro Omega System; NeuroSmart System

Indications for Use *(Describe)*

Neuro Omega System:
The Neuro Omega System with the incorporated 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 Neuro Omega System with the incorporated 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 a seizure disorder.

The Neuro Omega System with the incorporated installed HaGuide 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.

NeuroSmart System:
The NeuroSmart System with the incorporated HaGuide 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.

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

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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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Device Classification

For Neuro Omega:

Product Code:	GZL
Subsequent Product Code:	GWF, IKN, GWQ, GYC
CFR section:	21 CFR 882.1330
Regulation name:	Depth electrode
Trade Name:	Neuro Omega System
Common Name:	intraoperative neurophysiological Recording and Stimulating device
Classification:	Class II

For NeuroSmart:

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/NeuroSmart systems incorporated with HaGuide Software (as cleared under K220553)

2 Device Description – HaGuide Software

The cleared devices under K220553, the HaGuide Software incorporated in Neuro Omega/NeuroSmart systems, is designed to detect the STN region, it detects the entrance and exit boundaries of STN regions. Furthermore, it presents real-time graphs of power spectrum density and the normalized root mean square (nRMS) of the region.
The HaGuide Software consists of the following components:

- Patient Dashboard: The Patient Dashboard is comprised of a list of patients/cases that the user added, providing a user-friendly way to manage the surgery cases.
- Planning Setup: The Planning Setup is used by the user to setup the surgery planning.
- Trajectory Setup: The Trajectory Setup is used by the user to setup trajectory.
- MER/HaGuide: MER/HaGuide is comprised of:
    - Real-time Microelectrode Recording (MER) signal processing, presented as Normalized Root Mean Square (NRMS) and Power Spectrum Density (PSD) graphs, to assist the user to interpret the signals.
    - MER notes taking – adding notes and tags to specific site location to document and annotate the signals.
    - HaGuide Recommendation: Detection of the Subthalamic Nucleus (STN) borders, including the Intra STN detection of Dorsolateral Oscillatory Region (DLOR) and Ventromedial Non-Oscillatory Region (VMNR) boundary.
- Operation Room Report Upload – Cloud: The OR report uploading feature is used to export the case data and HaGuide graphs and HaGuide recommendation securely to the cloud.
- Raw Data Upload – Cloud: The raw data uploading feature is used to upload the raw recording data files securely to the cloud for offline processing

The HaGuide Software can work in three setups:

1. The HaGuide Software can be installed on the Neuro Omega/NeuroSmart PC and used on the system.
2. The HaGuide Software can be installed on an external PC as a standalone software for the purpose of working in off-line mode with no connection to the system.

In all setups the safety and effectiveness of the Neuro Omega/NeuroSmart systems isn't compromised, as the HaGuide Software is a non-blocking software (it doesn't affect the system's functionality even in malfunction). The HaGuide Software can run on both modes without affecting the Neuro Omega/NeuroSmart systems safety and effectiveness, nor its functionality.

The main use of the HaGuide Software when it runs as a standalone software, is for visual purpose only, meaning 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). In addition, system status and alerts will be uploaded to the cloud to serve AO customer support by monitoring the system status and providing preventive alerts. It is important to note that during the surgery the alerts are gathered and they are uploaded to the cloud as a report after the surgery completion, therefore the case is not interrupted by any mean.

3 Intended Use of Device

This 510(K) submission is focused on the HaGuide Software as standalone software but since the HaGuide serves the Neuro Omega/NeuroSmart systems, the intended use is unified with Neuro Omega/ NeuroSmart intended use.

3.1 Neuro Omega

The Neuro Omega system with the incorporated 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 Neuro Omega System with the incorporated 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 a seizure disorder.

The Neuro Omega with the incorporated installed HaGuide 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 HaGuide 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 device, Neuro Omega/NeuroSmart systems incorporated with HaGuide Software, is substantially equivalent to the predicate device HaGuide Software incorporated within the Neuro Omega/NeuroSmart systems and as stand alone, as cleared under **(K220553).**

The intended use and indications of the proposed HaGuide Software serves the Neuro Omega/NeuroSmart Systems. Therefore, the intended use is unified with Neuro Omega/ NeuroSmart intended use and identical to the legally marketed Neuro Omega/NeuroSmart Systems (**K220553**).

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 – HaGuide Software:

#	Comparison parameter	Subject device: HaGuide Software	Predicate device: Neuro Omega/NeuroSmart incorporated with the HaGuide Software	SE comparison discussion
1	**Legally distribution clearance No.**	**Subject device**	**K220553**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	
3	Operating System	Windows 10,11 64bit	Same	Similarity Identical for the subject device and the predicate Differences None
4	Communication protocols	HTTPS and FTPS secured protocols	Same	Similarity Identical for the subject device and the predicate Differences None
5	Software version	HaGuide Software V6.0.0	HaGuide Software (previously named Navigation Tool) V4.0.8	Similarity The purpose of the software is Identical for

#	Comparison parameter	Subject device: HaGuide Software	Predicate device: Neuro Omega/NeuroSmart incorporated with the HaGuide Software	SE comparison discussion
				the subject device and the predicate <u>Differences</u> new infrastructure and GUI but the purpose still the same, also risks and security aspects, were taken into consideration during the Risk management phase, and covered all the Hazards.

5 Summary of non-clinical performance tests:

Test Performed	Test Method/Applicable Standards	Acceptance Criteria	Unexpected Results/Significant	Results
Software /System Verification	This verification performed on the HaGuide Software, and checked that the design output meets the SW design input. This Verification was conducted similar to the reports that were presented in previous submission under K220553. The verification was made according to: • ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes • ISO 14971: 2019 Medical devices -	The acceptance criteria were defined according to the use cases and regressions tests performed by the Neuro omega / NeuroSmart systems, to ensure proper functionality: HaGuide SW integration with Alpha Omega cloud is tested. The verification tests cover the design inputs (SRS) as well as use cases and sanity tests.	--	All tests passed the acceptance criteria

Test Performed	Test Method/Applicable Standards	Acceptance Criteria	Unexpected Results/Significant	Results
	Application of risk management to medical devices • IEC 62304:2006/A12015 Medical device software - Software life cycle processes			
Penetration Testing	The cybersecurity risk management activities for the Neuro Omega/ NeuroSmart Systems and HaGuide Software, was conducted in compliance with AAMI TIR57 and NIST SP 800-30. The execution of this assessment resulted in a risk analysis, risk evaluation, risk acceptability, and security control implementation/traceability, and a summary of cybersecurity-related labelling.	The identified risks are determined, than the scales are passed in accordance to NIST SP 800-30r1.	--	Overall cybersecurity risks related to Confidentiality, Integrity, and Availability have been evaluated. This includes risks related to software supply chain. Any risks introduced by risk controls were evaluated and mitigated to an acceptable level
EMC Reports based on IEC 60601-1-2	Alpha Omega conducted EMC tests for the Neuro Omega and NeuroSmart incorporated the HaGuide Software according to IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for	the subject devices are safe and effective and meet the requirements of IEC 60601-1-2:2014, IEC 60601-1-2:014/AMD1:2020	--	All tests passed the acceptance criteria

Test Performed	Test Method/Applicable Standards	Acceptance Criteria	Unexpected Results/Significant	Results
	basic safety and essential performance Collateral Standard: Electromagnetic Compatibility and checked that the design output meets the standard requirements			
Safety Reports based on IEC 60601-1	Alpha Omega conducted Safety tests for the Neuro Omega and NeuroSmart incorporated the HaGuide Software according to IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance and checked that the design output meets the standard requirements	Neuro Omega/NeuroSmart systems incorporated the HaGuide Software are safe and effective and meet the requirements of IEC 60601-IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	--	All tests passed the acceptance criteria

6 Conclusions

Based on the above, it is Alpha Omega's opinion that the proposed modified HaGuide Software incorporated within Neuro Omega/ NeuroSmart systems has been compared to the predicates (Neuro Omega/NeuroSmart incorporated with HaGuide Software) in terms of intended use, indications for use, components, principles of operation, technological characteristics, and safety features.