January 2, 2020

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

Re: K191739
Trade/Device Name: Sterile LeadConfirm
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth Electrode
Regulatory Class: Class II
Product Code: GZL
Dated: November 25, 2019
Received: December 2, 2019

Dear Mrs. 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. 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191739

Device Name
Sterile LeadConfirm

Indications for Use *(Describe)*
The Alpha Omega Disposable Sterile LeadConfirm for MER is intended to be used in neurosurgery for connecting a compatible DBS Lead to a compatible recording and stimulation device.

The Alpha Omega Disposable Sterile LeadConfirm for MER is indicated for assisting Neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of a compatible DBS Lead.

The Alpha Omega Disposable Sterile LeadConfirm should only be used to connect a compatible DBS Lead to a compatible recording and stimulation device.

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

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Submission contact person:

Mrs. Maysana Mousa
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Device Classification

Proprietary Device Name:	Sterile LeadConfirm
Common name:	lntraoperative neurophysiological recording and stimulating device
Product Code:	GZL
Classification Name:	Depth Electrode
Classification Regulation:	21 CFR 882.1330
Regulatory Class:	II

Predicate Devices

Sterile Disposable Recording Cables - K120098

Device Description

Alpha Omega's Sterile LeadConfirm cable and adaptor connects the DBS lead to Alpha Omega's approved physiological navigation systems for recording and stimulation system: Neuro Omega (K171581) and NeuroSmart (K172042).

The purpose of the submission is to introduce the Sterile LeadConfirm Cable and Adaptor, the subject devices are sterile Hardware only.

There are three types of the subject device, Alpha Omega's Sterile LeadConfirm Cables:

1) Sterile LeadConfirm M Cable that connects to Medtronic Lead P960009 (3389, 3387)
2) Sterile LeadConfirm B Cable that connects to Boston Scientific Lead P150031 (BSC-DB-2201, BSC-DB-2202)
3) Sterile LeadConfirm A Cable that connects to Abbott Lead P140009 (6170/ 6171/ 6172/ 6173/ 6178/ 6170/ 6180/ 6181)

In addition, there are two types of Sterile LeadConfirm Adaptors:

1) Sterile LeadConfirm M Adaptor
2) Sterile LeadConfirm A Adaptor

AOE (Alpha Omega Engineering) stimulation with LeadConfirm cable and adaptor is identical to IPG/ test stimulator, with the following parameters:

a) Pulse shape: Square wave, Lili pulse
b) Amplitude up to 12mA
c) Duration up to 500µSec

Indications for Use Statement

The Alpha Omega Disposable Sterile LeadConfirm for MER is intended to be used in neurosurgery for connecting a compatible DBS Lead to a compatible recording and stimulation device.

The Alpha Omega Disposable Sterile LeadConfirm for MER is indicated for assisting Neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of a compatible DBS Lead.

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The Alpha Omega Disposable Sterile LeadConfirm should only be used to connect a compatible DBS Lead to a compatible recording and stimulation device

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Safety & Effectiveness

The Sterile LeadConfirm devices have been compared to the predicate device, Sterile Disposable Recording Cables (under K120098), in terms of intended use, indications for use, components, principles of operation, technological characteristics and safety features.

- **Intended Use Comparison**

#	Comparison parameter	Subject device: Sterile LeadConfirm	Predicate device: Sterile Disposable Recording Cables	Substantial Equivalent discussion
1	**Legally distribution clearance No.**	**Subject device**	**K120098**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	
3	Intended use and indications for use.	The Alpha Omega Disposable Sterile LeadConfirm for MER is intended to be used in neurosurgery for connecting a compatible DBS Lead to a compatible recording and stimulation device. The Alpha Omega Disposable Sterile LeadConfirm for MER is indicated for assisting	Alpha Omega's Sterile Disposable Recording Cables for MER are intended to be used in neurosurgery for connecting NeuroProbes to recording and stimulation device.	Similarities: Similar Differences: None

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#	Comparison parameter	Subject device: Sterile LeadConfirm	Predicate device: Sterile Disposable Recording Cables	Substantial Equivalent discussion
		Neurosurgeons, in the operating room during functional neurosurgery, to aid in the placement of a compatible DBS Lead. The Alpha Omega Disposable Sterile LeadConfirm should only be used to connect a compatible DBS Lead to a compatible recording and stimulation device		
4	indications for use and environment	Alpha Omega's Disposable Sterile LeadConfirm for MER is indicated for assisting Neurosurgeons, in the operation room during functional neurosurgery, to aid in placement of Lead.	Alpha Omega's Sterile Disposable Recording Cables for MER are indicated for assisting Neurosurgeons, in the operation room during functional neurosurgery, to aid in placement of depth electrodes.	Similarities: Similar Differences: None
5	Device code and regulation	**Product Code:** GZL **Regulation #**: 21CFR882.1330	**Product Code:** GZL **Regulation #**: 21CFR882.1330	Similarities: Identical Differences: None

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- **Performance Comparison**

#	Comparison parameter	Subject device: Sterile LeadConfirm	Predicate device: Sterile Disposable Recording Cables	Substantial Equivalent discussion
1	**Legally distribution clearance No.**	**Subject device**	**K120098**	
2	**Owner**	**Alpha Omega Engineering Ltd.**	**Alpha Omega Engineering Ltd.**	
3	Target treatment Population	All patients that need functional neurosurgery	All patients that need functional neurosurgery	Similarities: Identical Differences: None
4	Human Factors	Used by professional Neurosurgeons	Used by professional Neurosurgeons	Similarities: Identical Differences: None
5	Use environment	Operating Room	Operating Room	Similarities: Identical Differences: None

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#	Comparison parameter	Subject device: Sterile LeadConfirm	Predicate device: Sterile Disposable Recording Cables	Substantial Equivalent discussion
6	Integrity of materials and functionality after sterilization	Functionality and materials stability, including packaging verified, after irradiation sterilization.	Functionality and materials stability, including packaging verified, after irradiation sterilization.	Similarities: Identical Differences: None
7	Sterility achievement method	Sterilized by Alpha omega using irradiation sterilization and delivered sterile, validated process	Sterilized by Alpha omega using irradiation sterilization and delivered sterile.	Similarities: Identical Differences: None

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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 Sterile LeadConfirm devices have been compared to the predicate and reference device in terms of intended use, indications for use, components, principles of operation, technological characteristics and safety features.
Based on the performance results provided in this submission (including test results and clinical data) and the analysis of similarities and differences presented above, Alpha Omega believes that the proposed device is substantially equivalent to the predicate device without raising new safety and/or effectiveness issues.

Substantial Equivalence Statement

Based on the above, it is Alpha Omega's opinion that the proposed Sterile LeadConfirm devices are substantially equivalent in terms of design principles, performance features and of safety & effectiveness to the predicate legally cleared devices referred to in section 4 of this document.

Non Clinical and Clinical validation data

Verification and validation bench tests were performed, to demonstrate the safety and effectiveness of the proposed Sterile LeadConfirm devices.
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 predicate device to the subject device, results show that with the above intended use, the device is equivalent in safety and effectiveness.

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

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Performance Tests

Test	Test Method Summary	Results
Verification and Validation	This verification performed on complete Sterile LeadConfirm devices, the subject devices, and checked that the design output meets the design input	Sterile LeadConfirm devices have been verified under a complete verification plan traceable to Sterile LeadConfirm design input. All samples passed the acceptance criteria which determines the effectiveness of Sterile LeadConfirm devices.
Sterilization Validation LeadConfirm Adaptors final Report	This Sterilization validation performed on complete Sterile LeadConfirm Adaptors	The purpose of the study was to validate the effectiveness of the Gamma Radiation Sterilization for Alpha Omega Engineering Ltd. LeadConfirm adaptors, according to VDmax Method. According to the test results (section 13), the gamma radiation sterilization process of LeadConfirm Adaptors Cat. No. STR-000071-00, STR-000072-00 and STR-000073-00, at a sterilization dose of 20kGy, was sustained. This dose gave a SAL of 6 magnitudes as requested by the standards
Sterilization Validation LeadConfirm B Cable final Report	This Sterilization validation performed on complete Sterile LeadConfirm B Cable	The purpose of the study was to validate the effectiveness of the Gamma Radiation Sterilization for LeadConfirm B Cable, according to Vdmax Method. According to the test results (Section 13), the gamma radiation sterilization process of Electrodes lead cable, at a sterilization dose of 20kGy, was sustained. This dose gave a SAL of 6 magnitudes as requested by the standards
Sterilization Validation	This Sterilization validation performed on complete Sterile	The purpose of the study was to validate the effectiveness of the

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LeadConfirm M & A Cables final Report	LeadConfirm M & A Cables	Gamma Radiation Sterilization for LeadConfirm M & A Cables, according to Vdmax Method. According to the test results (Section 13), the gamma radiation sterilization process of Electrodes lead cable, at a sterilization dose of 20kGy, was sustained. This dose gave a SAL of 6 magnitudes as requested by the standards

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