February 14, 2020

Compumedics Limited
William Alam
Quality Engineering Manager
30-40 Flockhart Street
Abbotsford, 3067 Au

Re: K191785
Trade/Device Name: Orion LifeSpan™ MEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLY, GWQ, OLX
Dated: January 10, 2020
Received: January 13, 2020

Dear William Alam:

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, M.S.E.
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)*

K191785

Device Name
Orion LifeSpan MEG

Indications for Use *(Describe)*

The Orion LifeSpan MEG non-invasively measures the magnetoencephalographic (MEG) (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, and somatosensory in the brain when used in conjunction with evoked response averaging devices. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by the device may be used, in conjunction with other diagnostic data, as an aid in neurosurgical planning.

It is assumed that the users of the Orion LifeSpan™ MEG are physicians or neurology laboratory technicians who have received training in the following areas:

- Hospital procedures
- Physiological monitoring of patients
- Training relevant to the specific discipline or disorder under investigation

Note: This indication for use specifically excludes use of the Orion LifeSpan™ MEG as life support equipment, for example vital signs monitoring in intensive care units.

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

The following 510(k) summary is being submitted in accordance with 21CFR807.92.

Device Information:

Submitter:	Compumedics Limited
Address:	30-40 Flockhart Street, Abbotsford 3067, Victoria, Australia
Phone number:	+61 (0) 3 8420 7300
Fax number:	+61 (0) 3 8420 7399
Contact person:	William Alam 30-40 Flockhart Street, Abbotsford 3067, Victoria, Australia
Phone number:	+61 (0) 3 8420 7300
Fax number:	+61 (0) 3 8420 7399
Date prepared:	June 28, 2019
Trade name:	Orion LifeSpan™ MEG
Common name:	Magnetoencephalograph (MEG)
Primary product code:	OLY
Secondary product code:	GWQ, OLX
Device class:	II
Regulation numbers:	21 CFR 882.1400

Predicate Device Information:

Trade Name:	Elekta Neuromag
Manufacturer:	Elekta Neuromag Oy
510(k) number:	K041264
Product code:	OLY, GWQ, OLX
Device class:	II
Regulation numbers:	21 CFR 882.1400

Device Description

The Orion LifeSpan™ MEG is a magnetoencephalograph (MEG) which records magnetic signals from the human brain. The Orion LifeSpan™ MEG uses the CURRY software platform (K001781) to acquire, process and display these signals. Optionally EEG can be recorded simultaneously with the MEG using an integrated SynAmps2 (K023771) hardware system.

The Orion LifeSpan™ MEG can optionally be provided with adult, child or both sized helmets.

The Orion LifeSpan™ MEG is used by skilled operators or physicians trained in the acquisition and interpretation of such signals. It is used as an adjunct as part of a range of measurements performed, such as imaging and other studies, to form a more complete picture of the patient's pathology alongside a standard clinical workup.

Indications for Use

The Orion LifeSpan™ MEG non-invasively measures the magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, and somatosensory in the brain when used in conjunction with evoked response stimulators. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, as an aid in neurosurgical planning.

It is assumed that the users of the Orion LifeSpan™ MEG are physicians or neurology laboratory technicians who have received training in the following areas:

*Hospital procedures

*Physiological monitoring of patients

*Training relevant to the specific discipline or disorder under investigation

Note: This indication for use specifically excludes use of the Orion LifeSpan™ MEG as life support equipment, for example vital signs monitoring in intensive care units.

Substantial Equivalence Discussion

The following technological differences exist between the Orion LifeSpan™ MEG and Elekta Neuromag.

Orion LifeSpan™ MEG (K191785)	Elekta Neuromag (K041264)	Differences (if any)
Indications for use		
The Orion LifeSpan™ MEG non-invasively measures the magnetoencephalographic (MEG) signals (and, optionally, electroencephalographic (EEG) signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. MEG is routinely used to identify the locations of visual, auditory, and somatosensory in the brain when used in conjunction with evoked response stimulators. MEG is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by MEG may be used, in conjunction with other diagnostic data, as an aid in neurosurgical planning. It is assumed that the users of the Orion LifeSpan™ MEG are physicians or neurology laboratory technicians who have received training in the following areas: *Hospital procedures *Physiological monitoring of patients *Training relevant to the specific discipline or disorder under investigation Note: This indication for use specifically excludes use of the Orion LifeSpan™ MEG as life support equipment, for example vital signs monitoring in intensive care units.	The Elekta Neuromag non-invasively measures the magnetoencephalographic (meg) signals (and, optionally, electroencephalographic eeg signals) produced by electrically active tissue of the brain. These signals are recorded by a computerized data acquisition system, displayed, and may then be interpreted by trained physicians to help localize these active areas. The locations may then be correlated with anatomical information of the brain. Meg is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain. Meg is also used to non-invasively locate regions of epileptic activity within the brain. The localization information provided by meg may be used, in conjunction with other diagnostic data, in neurosurgical planning.	No significant difference, except the Orion LifeSpan™ MEG is not recommended for use with motor evoked response stimulators. Assumptions regarding evoked response stimulators, the types of users permitted, and use case exclusions are made more explicitly clear to further ensure safe usage.

Features	Orion LifeSpan™ MEG (K191785)	Elekta Neuromag (K041264)	Differences (if any)
Technology			
Site of patient	Head and Scalp	Head and Scalp	No difference.
Patient Position	Supine	Supine and upright	No significant difference. Upright position is available mostly for research purposes. Supine position is common for MEG study.
Underlying Technology	Superconducting magnetometry	Superconducting magnetometry	No difference.
Overall Sensitivity	$10\text{fT}/\sqrt{\text{Hz}}$	$10\text{fT}/\sqrt{\text{Hz}}$	No difference. See Non-Clinical Performance Data.
MEG Sensing Locations	186 (adult) 138 (pediatric)	102	No significant difference.
SQUID Readout	Flux locked loop	Flux locked loop	No difference.

Features	Orion LifeSpan™ MEG (K191785)	Elekta Neuromag (K041264)	Differences (if any)
Pickup Coil Design	Axial gradiometer	Mix of planar gradiometers and magnetometers	Despite difference in orientation, each pickup coil type measures components of the magnetic field generated from the same brain sources. During source estimation these signals are converted to (for example) equivalent current dipole locations, orientations and strengths. Therefore, there is no significant difference arising from the pickup coil designs.
Average Coil-to-Coil Spacing	27.3 mm (Adult), 25 mm (Pediatric) average distance b/w centers of each sensing loc.	34 mm average distance between centers of each sensing location.	No difference. See Non-Clinical Performance Data for discussion of localization accuracy testing.
Detector Architecture	DROS SQUID	dc SQUID	No significant difference. DROS SQUID is a type of dc SQUID.
Interference Elimination (i.e., SSS, SPS)	SSP, DSSP	SSP, tSSS (which has superseded SSS)	Note that DSSP is conceptually equivalent to tSSS in that it uses temporal information to separate interference from signal.[1] Therefore, no significant difference.
Head Position Indicator (Y/N)	Y	Y	No difference.

[1] Sekihara, K., Kawabata, Y., Ushio, S., Sumiya, S., Kawabata, S., Adachi, Y. and Nagarajan, S.S., 2016. Dual signal subspace projection (DSSP): a novel algorithm for removing large interference in biomagnetic measurements. *Journal of neural engineering*, *13*(3), p.036007.

Features	Orion LifeSpan™ MEG (K191785)	Elekta Neuromag (K041264)	Differences (if any)
Offline Average Function to Process Raw Data	Y	Y	No difference.
Number of SQUID Sensor Elements	186 (adult) 138 (pediatric) Each at a unique location	306 at 102 unique locations	Phantom dipole localization accuracy has shown that sampling density is sufficient in the Orion. Therefore, no functionally significant difference is noted due to the number of SQUID elements.
Number of Auxiliary Channels for Other Types of Data (i.e., EEG)	Up to 256 unipolar and 16 bipolar EEG channels Up to 8 ADC channels.	Up to 124 unipolar and 4 bipolar EEG channels. Up to 8 ADC channels.	No significant difference, provided that 128 EEG channels are included with the Orion, instead of the maximum (256).
Method of Calculation (i.e., idealized v. individual head model)	Spherical conductor model for idealized head shapes. Individual realistic head models using the Boundary Element Method (BEM).	Spherical conductor model for idealized head shapes. Individual realistic head models using the Boundary Element Method (BEM).	No difference.

Features	Orion LifeSpan™ MEG (K191785)	Elekta Neuromag (K041264)	Differences (if any)
Source Estimate Methods	ECD for clinical analysis. Single- and multi-dipole time varying source estimates.	ECD for clinical analysis. Single- and multi-dipole time varying source estimates.	Equivalent Current Dipole (ECD) localization is the primary method of source calculation used in clinical MEG. Various other methods are available both from the CURRY software and in the software included with the Elekta MEG, but these are not generally used for clinical applications.
Forward (or inverse) head models	See above two rows/No differences		
Design			
Patient Population	Adult and pediatric	Adult	No significant difference. The pediatric helmet is simply the same as adult helmet except the number of sensor and size.
Coverage	Whole cortex	Whole cortex	No difference.
Cryogen Used	Liquid Helium	Liquid Helium	No difference.
Power Source	Mains power	Mains power	No difference.
Software	CURRY Multimodal Neuroimaging Software	Elekta Neuromag Data Acquisition Software	A clinical study that shows Elekta Neuromag is compatible with CURRY software can be found on document VOL_020_017.
Data Acquisition	SynAmps2	Inbuilt	A clinical study that shows Elekta Neuromag is compatible with SynAmps2 for data acquisition can be found on document VOL_020_017.

Features	Orion LifeSpan™ MEG (K191785)	Elekta Neuromag (K041264)	Differences (if any)
Minimum Room Height	2.1m	2.3 m	No significant difference.
60601-1 Classification	Type BF	Type BF	No difference.
Material			
Dewar Helmet Material	Fiberglass composite	Fiberglass composite	No difference.

Non-Clinical Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Test	Test method summary	Results
Empty-room noise performance comparison testing	Compare the noise floor of the Orion LifeSpan™ MEG to that of the Elekta Neuromag using spectral analysis.[2] The MEG system was activated in an empty magnetically shielded room (MSR), and noise spectra across clinically relevant frequencies (0.5-50 Hz, per the IEC 60601-2-26 standard) were recorded. The average noise level should not be greater than the (predicate).	The measured average noise performance was comparable to that of the Elekta Neuromag (**Orion**: 10.54 $fT_{rms}/\sqrt{Hz}$; **Elekta**: 11.31$fT_{rms}/\sqrt{Hz}$)
Phantom Comparison Test	Compare the localization accuracy of the Orion LifeSpan™ MEG and Elekta Neuromag by taking an identical phantom signal and recording it with both systems.[2] The average localization error and the maximum localization error needs to be less than one standard deviation away from that of the predicate (0.7mm, total error across all 3 dimensions).	The localization accuracy results were less than one standard deviation away from the Elekta Neuromag. The average localization error difference was 0.4mm (**Orion**: 2.3mm; **Elekta**: 1.9mm), and maximum localization error difference was 0.5mm (**Orion:** 4.22mm; **Elekta**: 3.72mm).

[2] The Elekta Neuromag TRIUX MEG was measured at Swinburne University of Technology. Data dated: November 6th, 2019

Device Compatibility Test	The Orion LifeSpan™ MEG was tested upon integration of compatible devices (HPI Coils, EEG System, and evoked response stimulators, including Somatosensory, Visual and Auditory). Standard empty room recordings with each compatible device configuration were made. The average noise level (around 100Hz) of each device configuration was compared with the reference noise threshold ($10fT_{rms}/\sqrt{Hz}$).	The empty room test results showed that the addition of each compatible device did not significantly increase the noise level of the Orion LifeSpan™ MEG when used without compatible devices, nor did integration of each device result in exceeding the noise threshold (at around 100Hz).
CURRY Software Verification and Validation tests	All relevant CURRY Software specifications were verified and validated in accordance with IEC 62304:2006.	CURRY Software verification and validation tests show that the CURRY Software supports the Orion device functionalities in a manner comparable to the predicate, (i.e.., processing, display, localization, MEG control functions).
Limited Channel Operation Test	Phantom localization testing was performed to demonstrate device functionality and ability to meet source localization accuracy criteria while operating at three different degrees of channel operation (95%, 90%, and 80% of full channel capacity). The average localization error needs to be below 2mm, and the maximum localization error needs to be below 4mm.	The limited channel operation test demonstrates the device functionality and ability to meet source localization accuracy criteria (**average localization error range**: 0.05-0.09mm; **maximum localization error range**: 0.14-0.17mm) when operating without 20% of its channels (80% full channel capacity).

Additionally, evaluations were conducted in accordance with the following performance standards:

- IEC 60601-1:2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 80601-2-26:2019 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- IEC 62304:2006 Medical device software – Software lifecycle process
- ISO 14971:2007 Medical devices – Application of risk management to medical devices

Clinical Performance Data

Clinical testing was not performed.

Conclusion

Based on the non-clinical performance, the Orion LifeSpan™ MEG was found to have a safety and effectiveness profile that is similar to the predicate device. The Orion LifeSpan™ MEG also demonstrates meeting the same minimum safety and performance requirements for medically acceptable, commercial MEGs.