May 15, 2024

Megin Oy
% Charles Neitzel
Principal Consultant
RQM+
2790 Mosside Blvd, Suite 800
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Re: K233985
Trade/Device Name: TRIUX™ neo; MEG*review*™
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLX, OLY
Dated: April 15, 2024
Received: April 15, 2024

Dear Charles Neitzel:

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.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233985

Device Name

TRIUX™ neo; MEGreview™

Indications for Use *(Describe)*

The TRIUX™ neo 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 cortices 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, in neurosurgical planning.

TRIUX™ neo may be used for patients of all ages as appropriate for magnetoencephalography.

MEGreview™ is used for detection and localization of epileptic spontaneous brain activity. In addition, MEGreview™ may be used for localization of eloquent cortex, such as visual, auditory, somatosensory, and motor functions. Results interpreted by a trained clinician in conjunction with other imaging modalities can contribute to presurgical evaluation.

MEGreview™ is intended for patients of all ages as appropriate for magnetoencephalography.

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.

510(k) Summary

DATE PREPARED

May 15, 2024

MANUFACTURER

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DEVICE INFORMATION

- Device trade name, or proprietary name: TRIUX™ neo and MEG*review*™
- Device common name: Magnetoencephalograph
- Classification: II
- Classification Name: Electroencephalograph
- Regulation number: 21 CFR 882.1400
- Primary Product Code: OLX
- Secondary Product Code: OLY
- Panel: Neurology

PREDICATE DEVICE IDENTIFICATION

TRIUX™ neo and MEG*review*™ are substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Product Codes*	*Primary Predicate*
K091393	Elekta Neuromag with MaxFilter Elekta Neuromag Oy	OLX, OLY	✓

DEVICE DESCRIPTION

TRIUX™ neo

TRIUX™ neo NM27000N (TRIUX™ neo below) is a magnetoencephalographic (MEG) device, designed to non-invasively detect and display biomagnetic signals produced by electrically active nerve tissue in the brain. This system enables diagnostic capabilities by providing information about the location of active nerve tissues relative to brain anatomy. It measures both MEG and electroencephalographic (EEG) signals, which are then recorded, displayed, and interpreted by trained clinicians to aid in neurosurgical planning and locating regions of epileptic activity.

TRIUX™ neo employs 306 SQUID (Superconducting Quantum Interference Device) detectors to measure magnetic signals with minimal distortion, allowing for localization of brain activity. The detectors are housed in a cryogenic Dewar vessel, along with an internal helium recycler to maintain optimal operating conditions.

The TRIUX™ neo system features a probe unit with a modular structure, a patient-support system with a couch and chair for various positioning needs, and an electronics setup housed outside the magnetically shielded room. The software component, MEG*flow*™, facilitates data acquisition, preprocessing, and analysis, and includes functionalities for clinical epilepsy workflows, MRI integration, and visualization tools.

MEG*review*™

MEG*review*™ is a software for off-line visualization, identification, and localization of brain activity measured with magnetoencephalography (MEG) and, optionally, visualization of brain activity measured with scalp electroencephalography (EEG). MEG*review*™ provides workflows for epilepsy focus localization and functional mapping including signal processing, source localization, integration with anatomical MRI and visualization of the results overlayed on anatomical information, as well as reporting and exporting the results.

MEG*review*™ is intended to be used with TRIUX™ neo or equivalent MEG devices.

INDICATIONS FOR USE

TRIUX™ neo

The TRIUX™ neo 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 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, in neurosurgical planning.

TRIUX™ neo may be used for patients of all ages as appropriate for magnetoencephalography.

MEG*review*™

MEG*review*™ is used for detection and localization of epileptic spontaneous brain activity. In addition, MEG*review*™ may be used for localization of eloquent cortex, such as visual, auditory, somatosensory, and motor functions. Results interpreted by a trained clinician in conjunction with other imaging modalities can contribute to presurgical evaluation.

MEGreview™ is intended for patients of all ages as appropriate for magnetoencephalography.

COMPARISON OF INDICATIONS FOR USE

TRIUX™ neo has identical Indications for use as the primary predicate Elekta Neuromag® with MaxFilter 2.1.

MEG*review*™ has similar Indications for use as the primary predicate Elekta Neuromag® with MaxFilter 2.1. The predicate device is the whole MEG system including hardware and software for both data acquisition and analysis, and MEG*review*™ is the analysis software only. While worded differently, the Indications for use for MEG*review*™ is the same as for the analysis software part of the predicate device; source localization of active brain areas (epileptic spontaneous activity or eloquent cortex).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices utilize the same principle of operation, which is to measure MEG signals which are interpreted by a trained clinician in conjunction with other imaging data to contribute to presurgical evaluation. MEG is routinely used to identify the locations of visual, auditory, somatosensory, and motor cortex in the brain when used in conjunction with evoked response averaging devices.

Attribute	Subject device TRIUX™ neo	Predicate device K091393 Elekta Neuromag® with MaxFilter 2.1
Operating system (user)	Windows	Unix
Digitization hardware	Polhemus FASTRAK and upgraded digitization chair	Polhemus FASTRAK and digitization chair
Patient Position	Supine, reclined and upright	Supine and reclined
Synchronized video recording during the scan	Yes	No

GUI	Workflow-driven for entire acquisition process (e.g., patient creation, digitization, acquisition, saving data, etc.)	No workflow
Support for interference suppression	Yes, SSS-technology for suppression of environment and near-by interference (tSSS) and motion disturbances	Yes, SSS-technology for suppression of environment and near-by interference (tSSS)
Data compensation if patient moves	Yes, SSS-based head movement compensation	No movement compensation
Data storage	Patient-centric database that allows the user to store and access MEG/EEG scans, together with relevant metadata. This includes raw and preprocessed scans, video MEG, anatomical scans (MRI) and corresponding analysis results.	File-based
API	MEGflow™ scan acquisition system and data management server has been developed to support "plug-in" mapping applications and REST-API interface layer for data acquisition, scan control, database access, and user authentication.	No API
Auxiliary Channels	- 12 auxiliary analog inputs - 12 bipolar analog input channels for physiological signals	- 8 auxiliary analog inputs - 4 bipolar analog input channels for physiological signals
Attribute	Subject device MEG*review*™	Predicate device K091393 Elekta Neuromag® with MaxFilter 2.1
Operating system	Windows	Unix
Data access	Patient-centric	File-based
GUI	Workflow-driven	Several separate tools, no workflow
Availability of patient video	Synchronized video with data	No video available
Method of Calculation / Forward head model (i.e., idealized v. individual head model)	Spherical conductor model for idealized head shapes.	Spherical conductor model for idealized head shapes. Boundary element method (BEM) for individual head shapes.
Source Estimate Methods / Inverse head model	Equivalent Current Dipole (ECD) for clinical analysis. Single-dipole time varying source estimates.	Equivalent Current Dipole (ECD) for clinical analysis. Single- and multi-dipole time varying source estimates.

SUMMARY OF TESTING

The following tests were performed to demonstrate safety based on current industry standards:

TRIUX™ neo

- General requirements for basic safety and essential performance of medical electrical equipment per IEC 60601-1
- Electromagnetic compatibility requirements and tests per IEC 60601-1-2
- Software verification per IEC 62304 requirements – including the verification of MaxFilter
- Verification and Validation of the system and subsystem requirements

MEG*review*™

- Software verification per IEC 62304
- Acceptance testing and system verification
- Verification of MEG*review*™ Localization Accuracy (see below)

Phantom testing

Phantom test data were utilized in validation studies of the head movement compensation (MC) function. Signals generated by eight artificial dipole sources (one by one) in a spherical phantom were recorded with continuous rotations around the z-axis, or temporary movements by doing a rotation and translation repeated twice during a recording. The data were processed twice, first with the temporal Signal Space Separation (tSSS) method for interference suppression, and second time with combined tSSS and MC. A single equivalent current dipole (ECD) source in a spherical head model was applied for the source localization and the results were compared to exactly known dipole positions and amplitudes. The effect of the movement was clearly demonstrated in the dipole localizations without MC, resulting in large errors of dipole locations and amplitudes. The combined tSSS+MC restored the dipole localization accuracies to a similar level as from the corresponding phantom dipole sources when the phantom was not moved.

Clinical Investigations

A clinical investigation was performed with MaxFilter™ software in processing brain signals in evoked response studies. Twenty healthy adult (age 23 – 38, mean 30 years) and ten child (age 3 – 12, mean 7 years) volunteers were studied with two magnetoencephalographic (MEG) systems. Four recordings were done with both systems and the subjects were asked to: keep a stationary head position, change the head position twice during the recording, move the head continuously, and move the head and mouth when two magnetized pieces were attached to the scalp. During the MEG recordings the subjects received interleaved auditory and somatosensory stimuli. The source localization results were compared to the localization obtained from recordings with stationary head position without MC as obtained using the predicate localization software. In all trials with somatosensory responses and in temporary movements with auditory responses, the combined tSSS+MC yielded similar results to the predicate, as indicated by mean difference

in localization of the resulting dipoles of less than 10 mm. However, continuous head movements caused distortions of auditory evoked signals due to strong background activation of the motor cortex and muscles moving the head. Still, the somatosensory responses in these trials were much less affected than the auditory responses. The results show that evoked responses obtained after processing data with MaxFilter™ can be regarded as equivalent with those obtained with the predicate device, based on the acceptance criteria listed above. Another clinical investigation was carried out by analyzing MEG recordings from five pediatric epilepsy patients (age between 8 months and 15 years). Effects of movement were examined by studying MEG data exhibiting focal or multifocal interictal epileptiform discharges (IEDs). The results show that compensation of temporary head movements can provide localization of the irritative zone equivalent to that obtained when patients exhibit little-to-no motion. The findings demonstrate that the application of MC to pediatric MEG recordings containing variable degrees of spontaneous, temporary head movements (less than 25 mm head movement) can provide localization of the irritative zone equivalent to that obtained when patients exhibit little-to-no motion (less than 5 mm head movement).

Verification of MEG*review*™ localization accuracy

Measured phantom data and simulated epileptiform MEG signals were utilized for the verification of accuracy in MEG*review*™ localization of equivalent current dipoles (ECD). All dipole localizations were compared to the results from Xfit software in the predicate device. The overall localization errors were very similar between MEG*review*™ and Xfit. Both programs could localize phantom dipoles with less than 5 mm errors and with similar dipole amplitudes and statistical parameter values. Simulated epileptiform signals were superposed with resting state brain activity, and the localization accuracy was found to be equivalent between MEG*review*™ and Xfit. The results demonstrate that the ECD localization accuracy of MEG*review*™ is on a level which is clinically valuable.

Summary

All software verification testing and bench testing have demonstrated that the subject device fulfills the essential performance, and the spatial accuracy is equal or better than ±5 mm with known source locations in phantom measurement.

Clinical investigations have demonstrated that the subject device enables successful localization of evoked responses and epileptiform events in presence of temporary head movements without compromising the dipole quality statistics or signal-to-noise ratio, and the localization of events is equivalent to the localization with predicate device.

Together, these clinical studies and technical evaluations suggest that in the case of limited head movement during a patient measurement, the movement compensation functionality, particularly when combined with spatiotemporal signal space separation, preserves the signal quality for data analysis and reduces the localization error.

The results of these tests indicate that TRIUX™ neo NM27000N and MEG*review*™ are substantially equivalent to the predicate device K091393.

CONCLUSION

Based on the testing performed, including software testing and non-clinical performance bench testing, it can be concluded that TRIUX™ neo NM27000N and MEG*review*™ are substantially equivalent to the predicate device. TRIUX™ neo NM27000N and MEG*review*™ together have the same intended use and similar technological characteristics as the predicate device.