July 2, 2021

RICOH COMPANY, Ltd.
Satoshi Yuuki
Specialist
2-3, Hokuyodai
Kanazawa-shi, Ishikawa 920-0177
Japan

Re: K210199
Trade/Device Name: RICOH MEG
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLX, OLY
Dated: May 17, 2021
Received: May 26, 2021

Dear Satoshi Yuuki:

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

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)*
K210199

Device Name
RICOH MEG

Indications for Use *(Describe)*
The RICOH MEG non-invasively measures the magnetoencephalographic (MEG) 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 activity 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.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

## I. Submitter Information

Name: RICOH COMPANY, Ltd.
Address: 2-3, Hokuyodai, Kanazawa-shi, Ishikawa 920-0177 Japan
Phone: +81-76-258-7012
Facsimile: +81-76-258-7026
Contact Person: Satoshi Yuuki
E-Mail: satoshi.yuuki@jp.ricoh.com
Date: Jan 12 2021

## II. Device

Trade Name: RICOH MEG
Common Name: Magnetoencephalograph (MEG)
Classification Name(s): Electroencephalograph
Regulation numbers: 21 CFR 882.1400
Primary product code: OLX
Secondary product code: OLY
Device class: II

## III. Predicate Device(s)

| Device Name | 510(k) No. | Manufacturer |
|---|---|---|
| MEGvision, EQ1000C Series | K040051 | Eagle Technology, Inc. |
| Elekta Neuromag | K041264 | Elekta Neuromag Oy |

## IV. Device Description

The RICOH MEG Analysis is an analysis software package used for processing and analyzing MEG data. It displays digitized MEG signals, EEG signals, topographic maps, and registered MRI images. Universal functions such as data retrieval, storage, management, querying and listing, and output are handled by the basic MEGvision Software of Eagle Technology, Inc. (K040051).

The RICOH MEG Analysis is designed to aid clinicians in the assessment of patient anatomy, physiology, electrophysiology and pathology and to visualize source localization of MEG signals.

## V. Indications For Use

The RICOH MEG non-invasively measures the magnetoencephalographic (MEG) 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 activity 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.

## VI. Comparison of Technological Characteristics with the Predicate Devices

At a high level, the following technological differences exist between the subject and predicate devices:

- Use of a third party digitizer to provide additional method of co-registering MRI and MEG data;
- Number of auxiliary channels for other types of data (i.e., addition of cables and interface allowing subject device to receive and send digital EEG signals);
- Removal of evoked mode recording with post averaging;
- Updated display to show EEG time series at corresponding latency (if EEG data simultaneously acquired);
- Addition of DICOM data output with information regarding magnetic field anlaysis

| Feature | RICOH COMPANY, LTD.<br>RICOH MEG | EAGLE TECHNOLOGY, INC.<br>MEGvision EQ1000C Series<br>(K040051) | SE Device<br>Elekta Neuromag Oy<br>Elekta Neuromag<br>(K041264) |
|---|---|---|---|
| Intended Use | The **RICOH MEG** is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions. | **The MEGvision** non-invasively measures the magnetoencephalographic (MEG) signals produced by the electrical activities by the tissue activities of the brain. These signals, position, direction, and sensitivity of the sensors are acquired and displayed, and may be interpreted by trained clinicians to help localize these active areas. The locations may be correlated to anatomical structure of the brain. | **The Elekta Neuromag ™** is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained clinician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions. |

| Feature | RICOH COMPANY, LTD.<br>RICOH MEG | EAGLE TECHNOLOGY, INC.<br>MEGvision EQ1000C Series<br>(K040051) | SE Device<br>Elekta Neuromag Oy<br>Elekta Neuromag<br>(K041264) |
|---|---|---|---|
| Indications for use | The **RICOH MEG** non-invasively measures the magnetoencephalographic (MEG) 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 activity 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. | The **MEGvision** is intended for use as a magnetoencephalographic (MEG) device which non-invasively detects and displays biomagnetic signals produced by electrically active nerve tissue in the brain. When interpreted by a trained technician, the data enhances the diagnostic capability by providing useful information about the location relative to brain anatomy of active nerve tissue responsible for critical brain functions. | **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 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 MEG maybe used, in conjunction with other diagnostic data, in neurosurgical planning. |

| Feature | RICOH COMPANY, LTD.<br>RICOH MEG | EAGLE TECHNOLOGY, INC.<br>MEGvision EQ1000C Series<br>(K040051) | SE Device<br>Elekta Neuromag Oy<br>Elekta Neuromag<br>(K041264) |
|---|---|---|---|
| Number of SQUID detectors/ channels for MEG data | 64 to 320 | 64 to 320 | 306 |
| Operating Principle | dc SQUID | dc SQUID | dc SQUID |
| Number of auxiliary channels for other types of data | -16 ADC channels<br>-Up to 128 EEG channels (EEG system is independent of the MEG system). | Up to 166 ADC channels | Up to 124 unipolar and 4 bipolar EEG channels.<br>Up to 8 ADC channels. |
| Pickup Coil Design | 1 axial first order gradiometer per location | 1 axial first order gradiometer per location | Mix of planar gradiometers and magnetometers |
| Intersensor spacing | 20mm to 25mm<br>(160 sensor configuration) | 20mm to 25mm<br>(160 sensor configuration) | 34 mm average distance between centers of each sensing location. |
| Gradiometer placement | 64 to 320 | 64 to 320 | 102 |
| Cryogen used: | Liquid helium | Liquid helium | Liquid helium |
| Coverage | Whole cortex | Whole cortex | Whole cortex |
| Gantry | Floor mounted fixed gantry | Floor mounted fixed gantry | Floor mounted, standard gantry. The gantry has two fixed, predefined, tilt angles corresponding to supine and upright measurement positions. |
| Patient Position | Supine | Supine | Supine and upright |
| Head Position Indicator (HPI) | Included | Included | Included |
| Computer | Personal computer with Windows OS | Personal computer with Windows OS | HP workstation with UNIX OS |
| Networking Capabilities | Ethernet connections to other network system available | Ethernet connections to other network system available | Ethernet connections to other network system available |
| Magneticall y Shielded Room Accessories | Interior DC lights, video camera and two-way intercom for patients | Interior DC lights, video camera and two-way intercom for patients | Interior DC lights, video camera and two-way intercom for patients |
| Coregistrati on of MEG data to MRI data | A method based on the method of picking up the position of the HPI coils from the MRI images.<br>A method based on the method using the position of the HPI coils and the anatomical landmarks on the head, which measured by a 3D digitizer. | A method based on the method of picking up the position of the HPI coils from the MRI images. | A method based on the method using the position of the HPI coils and the anatomical landmarks on the head, which measured by a 3D digitizer. |
| Site of patient | Head and Scalp | Head and Scalp | Head and Scalp |
| Overall Sensitivity | 10fT/√Hz | 10fT/√Hz | 10fT/√Hz |

| Feature | RICOH COMPANY, LTD.<br>RICOH MEG | EAGLE TECHNOLOGY, INC.<br>MEGvision EQ1000C Series<br>(K040051) | SE Device<br>Elekta Neuromag Oy<br>Elekta Neuromag<br>(K041264) |
|---|---|---|---|
| SQUID Readout | Flux locked loop | Flux locked loop | Flux locked loop |
| Offline Average Function to Process Raw Data | Yes | Yes | Yes |
| 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. | Spherical conductor model for idealized head shapes. Individual realistic head models using the Boundary Element Method (BEM). |
| Source Estimate Methods / Inverse head model | Equivalent Current Dipole (ECD) for clinical analysis. Single- and multi-dipole time varying source estimates. | Equivalent Current Dipole (ECD) for clinical analysis. Single- and multi-dipole time varying source estimates. | Equivalent Current Dipole (ECD) for clinical analysis. Single- and multi-dipole time varying source estimates. |
| Patient Population | Adult | Adult | Adult |
| Power Source | Mains power | Mains power | same |
| Data Acquisition | Inbuilt | Inbuilt | Inbuilt |

## VII. Performance Data

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

- Software verification and validation in accordance with IEC62304;
- Bench testing (see below)

| Bench test | Purpose of Testing | Remark | Summary of results |
|---|---|---|---|
| [1]Matching Module design test | Verify that the Matching Module meets the design specifications by a black box test. | Test using MEG system<br><br>Verify that the Matching Module meets module design specifications regarding<br>e image correction and alignment techniques of co-registration to MRI/3D digitizer data. | Satisfied the pass / fail criteria. Pass.<br>Planned test cases :39 Tested cases :39<br>Failures occurred :0<br>Failures corrected :0 |
| [2] Analysis System design test | Verify that the Analysis System meets the design specifications by a black box test. | Test using MEG system<br><br>Verify that the updated function does not affect the continued performance of the rest of our device. | Satisfied the pass / fail criteria. Pass.<br>Planned test cases :20 Tested cases :20<br>Failures occurred :0<br>Failures corrected :0 |
| [3] Analysis System Validation | Perform the validation by a person who can substitute the intended user.<br><br>**Substitutes**: Person in charge of validation. *A person who can operate the product without training. A person who has the knowledge to be able to instruct the user on the operation of the product.<br><br>**Provision of training**: no training is required prior to the evaluation and therefore will not be conducted.<br><br>**Method of collection of validation record**s: the person in charge of validation validates and records according to the implementation. | Test using MEG system<br><br>Validate product validity, usability validity, and software validity based on the Intended Use. | Pass/Fail<br>Description: Pass |

## VIII. Conclusions

Given the modifications made to the device, bench testing was performed to support substantial equivalence. The non-clinical data provided demonstrate that the device should perform as intended in the specified use conditions, and that the device performs comparably to the predicate devices that are currently marketed for the same intended use. In addition, potential hazards have been addressed by the Risk Management process to ensure risk mitigation during use of the device.