K070358

JUL 3 0 2007

510(K) Summary Page 1 of 2

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Contact: Frank Zanow, President
Date prepared: June 23, 2007

1. Trade Name: MaxInsight™
Common Name: Electroencephalograph Software
Classification Name: Electroencephalograph, product code 'OLX Regulation: 882.1400 Class of device: Class II.

2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : K041264, Elekta Neuromag, manufactured by Elekta Neuromag Oy

3. Description of device: The MaxInsight ™ software is a software-only product. It runs on a personal computer and requires no specialized hardware. It displays digitized MEG signals, topographic maps, etc. It displays electrical brain activity correlated to anatomical brain information, which is provided by means of either an idealized head model and an idealized MRI image or a subject's MRI image based head model and the subject's MRI images. These functions are all controlled and interpreted by the user. The MaxInsight software imports digital MEG and co-registered EEG data (in the Neuromag Functional Image File Format) and permits its visualization. The digitized MEG/EEG input is read from a file on the personal computer (or available across the network). The software also provides a report generator to transfer relevant information, such as patient and recording information, event information, topographic images and images of brain activity, to a printable document.

4. Intended use: The software is intended for use by a trained/qualified MEG technologist or physician on both adult and pediatric subjects for the visualization of human brain function by fusing a variety of magnetoencephalographic (MEG) and electroencephalographic (EEG) information with rendered images of either an idealized head model and an idealized magnetic resonance (MR) image or a subject's MR image based head model and the subject's MR images

5. Technological characteristics: Both MaxInsight™ and the data analysis software of Elekta Neuromag support the following digital MEG/EEG plots: MEG/EEG review, topographic magnetic fields, topographic voltage. Both require that the signal be digitized by a separate MEG/EEG acquisition system. MaxInsight is a software only product, whereas the analysis software package of Elekta Neuromag is part of a system to measure and analyze MEG and optionally EEG signals..

6. **Performance:** Predetermined software development processes were employed in the design and testing of this software product, and validation testing was performed to ensure compliance with the product specifications. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device. After analyzing both bench and clinical testing data, it is the conclusion of eemagine Medical Imaging Solutions GmbH that the MaxInsight™ software is as safe and effective as the predicate devices, has few technological differences, and has no new indication for use, thus rendering it substantially equivalent to the data analysis package of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Eemagine Medical Imaging Solutions GMBH
c/o Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

APR - 9 2012

Re: K070358
Trade/Device Name: Maxinsight™
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLX
Dated (Date on orig SE ltr): June 23, 2007
Received (Date on orig SE ltr): June 25, 2007

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of July 30, 2007.

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 (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070358

Device Name: MaxInsight™

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070358