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EXHIBIT 2

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eemagine Medical Imaging Solutions GmbH
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May 31, 2005

Contact: Frank Zanow, General Manager

1. **Identification of the Device**:
   Proprietary-Trade Name: Cognitrace
   Classification Name/Product Codes: GWQ, GWE, and GWJ
   Common/Usual Name: Electroencephalograph with evoked response stimulation

2. **Equivalent legally marketed devices**: This product is similar in function to the Nicolet Bravo (K991054) and employs the software for which we obtained clearance in K002631.

3. **Indications for Use (intended use)** : Intended to record and display EEG and EP (evoked potential) data in the clinic and hospital. It is intended to aid in the diagnosis and monitoring of potential disorders of the central and peripheral nervous system.

4. **Description of the Device**: Cognitrace provides a comprehensive EEG/ERP Data acquisition and analysis System. Cognitrace consists of the following components:
   - EEG/ERP amplifier
   - Power supply for EEG/ERP amplifier
   - eemagine EEG (K002631) software with Cognitrace extension modules
   - Stimulation unit

   Cognitrace can perform complete sets of measurements for neurology and psychiatry:
   - EEG:
   - Visual Evoked Potential (VEP)
   - Auditory Evoked Potential (AEP)
   - P300 (Auditory oddball paradigm)
   - Visual P300 (Visual oddball paradigm)
   - CNV (Contingent Negative Variation)
   - Option to add protocols using acoustic or visual stimulation.

   The software components are:
   - eemagine EEG, a novel, user-friendly and efficient software package for the analysis of EEG data and
   - eego, a novel, user-friendly EEG data acquisition system and allows you to record and review EEG, offering different amplifier configurations. eego is seemlessly integrated with the eemagine EEG software, which offers simplicity and efficiency in the analysis of EEG studies.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices. The hardware components have been evaluated and found to comply with the same safety and EMC compatibility standards as the predicate.

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6. Substantial Equivalence Chart

Feature	Nicolet Bravo Multi Modality System (K991054)	Cognitrace
INDICATIONS FOR USE	Intended to record and display EEG, EP, EMG and TCD data in the clinic and hospital (including the hospital room, operating room, emergency room, intensive care unit, neuro intensive care unit, critical care unit, etc.), and to import and display data from third-party monitoring devices such as vital signs monitors. It is intended to aid the diagnosis and monitoring of potential disorders of the central and peripheral nervous system and muscles.	Intended to record and display EEG and EP (evoked potential) data in the clinic and hospital. It is intended to aid in the diagnosis and monitoring of potential disorders of the central and peripheral nervous system.
Prescription Use	Yes	Yes
Testing Modes	EEG, EP, EMG	EEG, EP
Head Box:	Uses a headbox. Similar to Cognitrace but fewer channels (32) available	EEG: Various headboxes available for up to 128
Filters	Low filter: First order IIR digital filter High filter: Second order IIR digital filter Available sampling frequencies:< 1000 Hz Digital filter applied to display of EEG data	Inside the amplifier following filtering is performed: Highpass: none, Lowpass digital FIR filter, cutoff frequency = 0.27 * sample frequency Available sampling frequencies: 256 Hz, 512 Hz, 1024 Hz, 2048 Hz
Noise:	(0.1 -100 Hz) < 2 µV (p-p), (0.7 µVrms)	EEG, BIP inputs: noise < 1.0 µVrms AUX inputs: Noise < 20 µVrms
Software	Data Analysis ▪ Averaging ▪ Signal Processing ▪ Filtering (band pass, low pass, high pass, band stop) ▪ Artifact detection ▪ Baseline correction ▪ Averaging Data Acquisition Visualization	Data Analysis ▪ Averaging ▪ Dipole Fit ▪ Spike Detection ▪ Signal Processing ▪ Filtering (band pass, low pass, high pass, band stop) ▪ Artifact detection ▪ Baseline correction ▪ Averaging ▪ Grand averaging ▪ Detrending ▪ Resampling ▪ Spike detector ▪ Dipole Fit ▪ FFT ▪ Coherence ▪ Surface Laplacian Data IO (e.g. EEG data files) DICOM Import (medical Images) Graphical user interface Data Acquisition ▪ Montage (e.g. montage editor) ▪ EEG signal acquisition ▪ Writing of EEG data to file Visualization Reports and wizards (e.g. analysis reports) Screen calibration Visualization (e.g. EEG view to display EEG traces) HTML templates (e.g. for the definition of the acquisition and analysis workflow)
DISPLAY	Various sizes/options of color LCD	SAME
POWER SOURCE	120V ac	SAME

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7. **Conclusion**

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of eemagine Medical Imaging Solutions GmbH that the Cognitrace is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2005

eeMagine Medical Imaging Solutions GmbH
c/o Mr. Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield, Illinois 60015

Re: K051825
Trade/Device Name: Cognitrace
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: August 17, 2005
Received: August 26, 2005

Dear Mr. Kamm:

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. 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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051825

Indications for Use

510(k) Number (if known):

Device Name: Cognitrace

Indications For Use: Intended to record and display EEG and EP (evoked potential) data in the clinic and hospital. It is intended to aid in the diagnosis and monitoring of potential disorders of the central and peripheral nervous system.

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)

Mark N Milhorn

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

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