510(k):

510(k) Summary 510(k) Number K110223

1. **Submitter:**
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   Date Prepared: May 24, 2011
   Contact: Maarten van de Velde, PhD, Quality Assurance Manager

JUN 29 2011

2. **Identification of the Device:**
   Proprietary-Trade Name: WaveGuard™ EEG cap
   Classification Name: Product Code GXY
   Common/Usual Name: EEG Electrode Cap

3. **Equivalent legally marketed device**: Electro-cap, K780045 made by Electro-cap and Electrode Array Cap K071446, made by Electrode Arrays.

4. **Description of the Device**: WaveGuard caps consist of Cap fabric Electrodes arranged in a certain layout Chin-strap (placed under the chin) Cable bundle(s) with connector(s) The layout of the electrodes depends on the number of electrodes placed in the cap, and may be placed according to the international 10/20, 10/10 or 10/5 percent system, or according an equidistant "Duke" layout. Caps can have different sizes, ranging from neonatal size (23-weeks old) to large adult head-size, spanning a total of 11 different cap sizes. Here is a list:

Available cap sizes

Cap size indication		Minimum-Maximum head circumference (cm)		Minimum-Maximum (inches, approx. values)	
Large		56	61	22.0"	24.0"
Medium		51	56	20.1"	22.0"
Small		47	51	18.5"	20.1"
Child		43	47	16.9"	18.5"
Infant		39	43	15.4"	16.9"
Baby		36	39	14.2"	15.4"
Neonatal	5	33	36	13.0"	14.2"
	4	31	33	12.2"	13.0"
	3	29	31	11.4"	12.2"
	2	27	29	10.6"	11.4"
	1	25	27	9.8"	10.6"

5. **Indications for Use (intended use)** This is an EEG electrode set intended for routine clinical settings where rapid placement of large number or EEG electrodes is desired.

6. **Technological Characteristics**: This device has the same technological characteristics (i.e., design, material, chemical composition) as the predicate device. Specifications are nearly identical. The electrodes are made from sintered silver-silver chloride, identical to multiple similar devices used for EEG recording

7. **Discussion of the clinical and nonclinical tests in the premarket notification submission for a determination of substantial equivalence:** We performed electrical safety (IEC 60601-1) and biocompatibility testing: Test Report Cytotoxicity, -Proliferation EN ISO 10993-5, -12, Test Report Chemical analysis (characterization of organic leachables) EN ISO 10993-12, -18 and Evaluation Biological safety – toxicology (ISO 10993-1). Usability and risk analysis was also conducted. Electrical specifications were examined and found to be comparable to the predicate. Patient contact materials (silver/silver chloride electrodes) are identical to the predicate. Physical examination demonstrates the connectors comply with the FDA performance standard. A clinical investigation "High-fidelity recording of brain activity in the extremely preterm babies: Feasibility study in the incubator" concluded that all recordings were successful beginning from the very first baby recorded with this cap design.

8. **Conclusion**. Based on the results of the nonclinical tests (that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed devices) we conclude that this device is safe and effective as the predicate identified in paragraph (3). Furthermore, the materials and construction methods are nearly identical to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Eemagine Medical Imaging Solutions, GmbH
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
8870 Ravello Ct
Naples, FL 34114

JUN 29 2011

Re: K110223
Trade/Device Name: WaveGuard™ EEG Cap
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: II
Product Code: GXY
Dated: June 21, 2011
Received: June 27, 2011

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. 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); 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 Kesia Alexander

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): **K110223**

Device Name: WaveGuard™ EEG cap

Indications For Use:

This is an EEG electrode set intended for routine clinical settings where rapid placement of large number or EEG electrodes is desired.

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 In-vitro Diagnostics (OIVD)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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