November 25, 2024

eemagine Medical Imaging Solutions GmbH
Dana Coggin
Consultant
Quality and Regulatory Help, LLC.
115 Reeder St
Tillamook, Oregon 97141

Re: K240575
Trade/Device Name: WaveGuard Net EEG Cap (NA-245, NA-255, NA-261, NA-265, NA-271, NA-281)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 11, 2024
Received: October 11, 2024

Dear Dana Coggin:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240575

Device Name

WaveGuard Net EEG Cap (NA-245, NA-255, NA-261, NA-265, NA-271, NA-281)

Indications for Use *(Describe)*

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

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K240575

WaveGuard™ Net EEG cap - 510(K) Summary

prepared in accordance with 21 CFR 807.92

I. SUBMITTER:

Submitter name and address:	eemagine Medical Imaging Solutions GmbH Gubener Strasse 47 10243 Berlin, Germany Phone +49 (0)30 2904 8404 Fax +49 (0)30 2904 8405
Contact information:	Maarten van de Velde, PhD, Quality Assurance Manager Email: mvelde@ant-neuro.com Phone +49 (0)30 2904 8404

II. DEVICE INFORMATION:

Common name:	EEG Electrode cap
Proprietary-Trade Name(s):	WaveGuard™ Net EEG cap (NA-245, NA-255, NA-261, NA-265, NA-271, NA-281)
Classification:	Class II
Product Code:	GXY
Common / Usual Name:	EEG Electrode Cap
Intended use / 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. Patient population from infants up to any age.

III. PREDICATE DEVICE:

Predicate Device:	WaveGuard™ EEG cap K110223 Class II
Product code:	GXY
Clearance date:	June 29, 2011

IV. DEVICE DESCRIPTION:

WaveGuard™ Net EEG cap consists of Saline-based EEG electrolyte- soaked sponge electrodes made of PU substrate plated with Ag and arranged in 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 10/10, 10/20 or 10/5 percent system, or according an equidistant “Duke” layout. Caps can have different sizes, ranging from baby to large adult head-size, spanning a total of 6 different cap sizes.

V. 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. Patient population is intended to be used from infants up to any age .

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table is a comparison of the technological characteristics between the Modified and Predicate Device:

Characteristic	WaveGuard™ EEG Cap K110223 (predicate)	WaveGuard™ Net EEG Cap K240575 (modified)
Product Code	GXY	GXY
Regulation Number	882.1320	882.1320
Classification Name	Electrode, Cutaneous	Electrode, Cutaneous
Manufacturer	eemagine Medical Imaging Solutions GmbH	eemagine Medical Imaging Solutions GmbH
Intended use and indications for use	The WaveGuard™ EEG Cap is an EEG Electrode set intended for routine clinical settings where rapid placement of a large number of EEG electrodes is desired. Patient population from 23 weeks (gestational age) to old-age (no limit).	The WaveGuard™ EEG Cap is an EEG Electrode set intended for routine clinical settings where rapid placement of a large number of EEG electrodes is desired. Patient population from infant (29 days) up to any age.
Electrode Material and Housing	Sintered Ag/AgCl on Polyurethane (PU)	Coated Ag on Polyurethane (PU)
Cap material	Lycra	Silicone Mesh
Cap Sizes	Adult Large 56-62 cm Adult Medium 52-57 cm Adult Small 47-53 cm Child 42-48 cm Infant 38-44 cm Baby 35-39 cm Neonate 5: 33-36 cm Neonate 4: 31-33 cm Neonate 3: 29-31 cm Neonate 2: 27-29 cm Neonate 1: 25-27 cm	Adult Large 56-61 cm Adult Medium 51-56 cm Adult Small 47-51 cm Child 43-47 cm Infant 39-43 cm Baby* 36-39 cm * not an indication of the patient age.
Performance standard	21 CFR PART 898— Performance Standard for Electrode Lead wires and Patient Cables.	21 CFR PART 898— Performance Standard for Electrode Lead wires and Patient Cables.

Electrode Placement	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.	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.
Magnetic Resonance	MR safe, WaveGuard MRI cap	MR unsafe
Connector	Hirose high-density connector, DC37 or DB25 connector, or other standard connectors as available on EEG amplifiers	Additional standard EEG adapters compatible with the eego EE-2xx and EE-5xx range of amplifiers. No significant difference with existing adapter(s).
Accessory	Conductive Electrode Gel	Saline soaked
Re-use	Reusable after cleaning	Reusable after cleaning

VII. PERFORMANCE DATA / SUMMARY OF NON-CLINICAL TESTING

21 CFR PART 898—Performance Standard for Electrode Lead wires and Patient Cables.
Biocompatibility testing was completed to the FDA recognized standards:

- ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: valuation within a risk management process
- ISO 10993-5:2009, In vitro cytotoxicity
- ISO 10993-10:2021, Sensitization
- ISO 10993-12:2012, Sample preparation and reference materials
- ISO 10993-17:2023, Allowable limits for leachable substances
- ISO 10993-18: 2020, Chemical characterization
- ISO 10993-23:2021, Irritation

VIII. CONCLUSIONS

Based on the results of the non-clinical tests conducted which demonstrate that the device is as safe, effective, and performs as well as the current legally marketed device, we conclude that this device is safe and as effective as the predicate.