April 27, 2018

Memory MD INC
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, Guangdong, 510006 Cn

Re: K172866
Trade/Device Name: NeuroCap
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 7, 2018
Received: February 12, 2018

Dear Cassie Lee:

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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172866

Device Name
NeuroCap

Indications for Use *(Describe)*
The NeuroCap (model DEC18) is an Electroencephalogram (EEG) electrode array intended for use in ER (emergency room), ICU (intensive care unit) and OR (operating room) for recording of STAT EEGs in patients of 18 years of age and older.

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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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: MemoryMD INC
Establishment Registration Number: Applying
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Application Correspondent:

Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: NeuroCap
Model: DEC18
Common Name: Cutaneous electrode Disposable
Classification name: Cutaneous electrode Disposable
Review Panel: Neurology
Product Code: GXY
Regulation Class: 2
Regulation Number: 882.1320

3. Predicate Device Information

510(K) Number: K092828
Company Name: HydroDot, Inc.
Trade/Device Name: StatNet
Regulation Number: 882.1320
Regulatory Class: 2
Product Code: GXY

4. Device Description

The NeuroCap (model DEC18) is an Electroencephalogram (EEG) electrode array intended for use in ER (emergency room), ICU (intensive care unit) and OR (operating room) for recording of STAT EEGs in

patients of 18 years of age and older. NeuroCap is intended for use with amplifiers of medical signals equipped with appropriate plug or by special adapter (the adapter will not be included in subject device). NeuroCap is a disposable electrodes system made of polycarbonate based film with applied conductive paths and sensors. Each sensor is equipped with a sponge with a conductive gel for providing sensor contact with the skin surface. NeuroCap is fixed on the patient by means of adhesive tape. NeuroCap could be connected to amplifier directly or via a special adapter.
The NeuroCap disposable electrode system is 16 channels. The headband is non-sterile and disposable for single patient use and designed to be used with the Neuro EEG device (K173460) for EEG acquisition and recording. NeuroCap is intended for prescription use in healthcare facilities, or clinical research environments.

5. Intended Use / Indications for Use

The NeuroCap (model DEC18) is an Electroencephalogram (EEG) electrode array intended for use in ER (emergency room), ICU (intensive care unit) and OR (operating room) for recording of STAT EEGs in patients of 18 years of age and older.

6. Test Summary

The proposed NeuroCap has been evaluated the safety and performance by lab bench testing as following:

- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Risk management according to ISO 14971:2012 standards
- Performance test according to ANSI/AAMI EC12:2000 Disposable ECG electrodes standards

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the proposed NeuroCap is substantially equivalent to the predicate devices quoted below. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Remark
Device Name and Model	NeuroCap (Model: DEC18)	StatNet (model: 3100, 3110)	--
510(k) Number	Applying	K092828	--
Product Code	GXY	GXY	SE

Intended Use / Indications for Use	The NeuroCap (model DEC18) is an Electroencephalogram (EEG) electrode array intended for use in ER (emergency room), ICU (intensive care unit) and OR (operating room) for recording of STAT EEGs in patients of 18 years of age and older.	An Electroencephalogram (EEG) electrode array intended for use in the ER, ICU and OR for recording of STAT EEGs in patients of 18 years of age and older.	SE
Patient population	Adults only (>18 years old)	Adults only (>18 years old)	SE
User	Trained Technician	Trained Technician	SE
Number of electodes	18	18	SE
Electrode material	Ag/AgCl	Ag/AgCl	SE
Type of conducting medium	Conductive gel	Conductive gel	SE
Sizes of EEG - caps (by head circumference)	S (47-53 cm) M (50-56 cm) L (56-62 cm)	M (50-56) L (56-62)	SE Note 1
Surface area of each electrode	1.13 cm^2	1.56 cm^2	SE Note 1
Work duration after the package opening	4 hours	4 hours	SE
Storage life	18 months	18 months	SE
Package dimensions	less 490x460x15 mm	less 520x290x15 mm	SE Note 1
Net Weight	less 25 grams	less 40 grams	SE Note 1
Gross Weight	less 200 grams	less 80 grams	SE Note 1

* SE means " substantially equivalent".

Comparison in Detail(s):
Note 1: The "Sizes of EEG-caps", "Surface area of each electrode", "Net Weight", "Gross Weight", "Package Dimensions" have little difference between the subject device and the predicate one. They are all the appearance specifications and complying with the ISO 10993 biocompatibility requirements and ISO14971:2012 harm control application to medical device. Therefore, the differences between the two have no impacts on the safety and effect.

Finial Conclusion:
The subject product the NeuroCap is Substantial Equivalent to the predicate product.

8. Date of the summary prepared: April 27, 2018