March 5, 2021

Memory MD Inc
% Mike Corcoran
Principle
Mtak LLC
8241 Enclave Cove
Woodbury, Minnesota 55125

Re: K202913
Trade/Device Name: NeuroCap (Model DEC22)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 8, 2020
Received: December 9, 2020

Dear Mike Corcoran:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202913

Device Name
NeuroCap (Model DEC22)

Indications for Use *(Describe)*
The NeuroCap (Model DEC22) is an Electroencephalogram (EEG) electrode array intended for use in routine clinical and research settings where recording of STAT EEGs 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.

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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: 3014403523
Address: 125 Wilbur Place, Suite 170, Bohemia, NY, USA
Postal Code: 11716
Phone: (215) 341-6373
Contact Person (including title): Vadim Sakharov, Chief Technology Officer
E-mail: vadim@memorymd.com

Application Correspondent:
Contact Person: Mike Corcoran
Phone: 612-226-2915
Email: mcorcoran@memorymd.com

2. Subject Device Information

Common Name: Cutaneous electrode
Classification Name: Electrode, Cutaneous
Trade Name: NeuroCap
Model Name: DEC22
Product Code: GXY
Regulation Number: 882.1320
Regulatory Class: II
Review Panel: Neurology

3. Predicate Device Information

Predicate Device 1:
510(K) Number: K172866
Company Name: Memory MD INC
Common Name: Cutaneous electrode
Classification Name: Electrode, Cutaneous
Trade Name: NeuroCap
Model: DEC18
Regulation Number: 882.1320
Regulatory Class: II
Product Code: GXY

Predicate Device 2:
510(K) Number: K162460
Company Name: WAVi Co.
Common Name: Cutaneous electrode
Classification Name: Electrode, Cutaneous
Trade Name: WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts
Model: WH-100: XS Headset, WH-200: S Headset, WH-300: M Headset, WH-400: L Headset, WH-500: XL Headset
Regulation Number: 882.1320
Regulatory Class: II
Product Code: GXY

4. Device Description
NeuroCap is a disposable electrodes system made of polycarbonate-based film with applied conductive paths and sensors. Each Ag/AgCl sensor is equipped with a sponge that is coated with a conductive gel for providing sensor contact with the scalp (cutaneous) surface. NeuroCap is fixed on the patient by means of adhesive tape and Velcro. NeuroCap could be connected to a signal amplifier directly or via a special adapter. (The adapter will not be included in the subject device.) The practical application of the NeuroCap is in electroencephalography.

The NeuroCap disposable electrode system has 19 active channels. The headband of the device is non-sterile and disposable for single patient use. The NeuroCap is designed to be used with the Neuro EEG Device (K173460) for EEG acquisition and recording. The Neuro EEG Device is sold separately.

NeuroCap is intended for prescription use in healthcare facilities or clinical research environments. NeuroCap is not intended for current stimulation and must be used by qualified personnel.

5. Intended Use / Indications for Use
The NeuroCap (Model: DEC22) is an Electroencephalogram (EEG) electrode array intended for use in routine clinical and research settings where recording of STAT EEGs is desired.

6. Test Summary
The proposed NeuroCap has been evaluated for safety and performance using the 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 1	Predicate Device 2	Remark
Device Name and Model	NeuroCap (model DEC 22)	NeuroCap (model DEC 18)	WAVi™ Headset and WAVi™ eSoc™ Single Use Electrode Contacts (Models: WH-100: XS Headset, WH-200: S Headset, WH-300: M Headset, WH-400: L Headset, WH-500: XL Headset)	--
510(k) Number	K202913	K172866	K162460	--
Product Code	GXY	GXY	GXY	SE
Indications for Use	The NeuroCap (Model: DEC22) is an Electroencephalogram (EEG) electrode array indicated for use in routine clinical and research settings where recording of STAT EEGs is desired.	The NeuroCap (model DEC18) is an Electroencephalogram (EEG) electrode array indicated 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.	The WAVi Headset is intended for use in routine clinical and research settings where rapid placement of a number of EEG electrodes is desired.	SE Note 1
Intended for Use	The NeuroCap (Model: DEC22) is an Electroencephalogram (EEG) electrode array intended for use in routine clinical and research settings where recording of STAT EEGs is desired.	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.	The WAVi Headset is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	SE Note 2
Energy Source	Passive Electrodes, all energy from EEG amplifier(Neuro EEG Device)	Passive Electrodes, all energy from EEG amplifier (Neuro EEG Device)	Passive Electrodes, all energy from EEG amplifier	SE
Principle of Operation	Needs to transmit electrophysiological signals from an individual to data collection devices. Does not transmit electrical	Needs to transmit electrophysiological signals from an individual to data collection devices. Does not transmit electrical current, nor are	Needs to transmit electrophysiological signals from an individual to data collection devices. Does not transmit electrical current, nor are	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	current, nor are they intended to be used for stimulation.	they intended to be used for stimulation.	they intended to be used for stimulation.	
User	Trained Technician	Trained Technician	Not publicly available	SE
Number of Contacts	22	18	22	SE Note 3
Number of Recording Channels	19	16	19	SE Note 4
Electrode material	Ag/AgCl	Ag/AgCl	Nylon 6/6 (101) and Pure Tin	SE Note 5
Type of conducting medium	Conductive gel	Conductive gel	Not publicly available	SE
Sizes of EEG - caps (by head circumference)	XS (43-49 cm) S (47-53 cm) M (50-56 cm) L (56-62 cm)	S (47-53 cm) M (50-56 cm) L (56-62 cm)	Various- Extra Small to Extra Large	SE
Work duration after opening the package	4 hours	4 hours	Not publicly available	SE
Storage life	18 months	18 months	Not publicly available	SE
Biocompatibility	ISO 10993 series	ISO 10993 series	None was conducted	SE

* SE means “substantially equivalent”.

Comparison in Detail(s):

Note 1: (Indications for Use)

Although there are some slight differences in the wording of the “Indications for Use” between the subject device and predicate devices, all devices are indicated for use in patients that need the rapid placement of electrodes for EEG. No significant differences exist between the subject and predicate devices.

Note 2: (Intended Use)

Although there are some slight differences in the wording of the “Intended Use” between the subject device and predicate devices, all devices are used for similar purposes in similar patient populations. No significant differences exist between the subject and predicate devices.

Note 3: (Number of Contacts)

The subject device has 22 contacts. The NeuroCap DEC18 (predicate #1) has 18 contacts. The electrode material of these contacts is identical. The second predicate device (WAVi™ Headset) was included in this submission because it contains 22 contacts which is the same number as the subject device. The differences in the number of contacts listed above do not represent a significant difference between the subject and predicate devices.

Note 4: (Number of Recording Channels)
Like the explanation in Note 3 above; the subject device has 19 recording channels. The NeuroCap DEC18 (predicate #1) has 16 recording channels. The second predicate device (WAVi™ Headset) has 19 recording channels which is the same number as the subject device. The differences in the number of recording channels listed above do not represent a significant difference between the subject and predicate devices.

Note 5: (Electrode Material)
Some differences exist between the materials of the electrodes for the subject device and predicate devices. Although differences in materials exist, the function of the electrodes in each device is the same. These differences are not significant and do not raise any new safety or effectiveness concerns.

Conclusion:

The subject device has all features of the predicate devices. The slight differences between subject device and predicate devices do not raise any new safety and effectiveness concerns. Therefore, the subject device is substantially equivalent to the predicate devices (K172866 and K162460).

8. Date of the summary prepared: February 15, 2021