June 1, 2020

CONMED Corporation
Tessa Hopsicker
Senior Specialist, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K200540
Trade/Device Name: BRAINSTREAM Disposable Deep Cup EEG Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 2, 2020
Received: March 3, 2020

Dear Tessa Hopsicker:

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,

Amber T. Ballard -S

For Vivek Pinto, PhD
Director
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)*
K200540

Device Name
BRAINSTREAM Disposable Deep Cup EEG Electrodes

Indications for Use *(Describe)*
The single patient EEG Cup Electrode is intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals, for example: Electroencephalograph (EEG) and Nerve potentials signals. The electrodes are for single patient use only.

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 of Safety and Effectiveness

BRAINSTREAM™ Disposable Deep Cup EEG Electrodes by CONMED

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number _____ as of March 2, 2020.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Tessa Hopsicker
Senior Specialist, Regulatory Affairs
Telephone: (315) 624-3345
Fax: (315) 624-3225

C. Device Name

Proprietary Name:	BRAINSTREAM™ Disposable Deep Cup EEG Electrodes
Common Name:	Electrode, Cutaneous
Panel:	Neurology
Product Code:	GXY
Device Class:	II
Regulation Number:	21 CFR 882.1320

D. Predicate Device

Primary Device Name:	AMBU NEUROLINE SINGLE PATIENT EEG/EP CUP ELECTRODE
Company Name:	AMBU, INC.
510(k):	K032278

E. Device Description

A cutaneous electrode is an electrode that is applied directly to a patient's skin to record physiological (biopotential) signals. Cutaneous electrodes are used in the acquisition of signals for the purpose of monitoring and recording electroencephalograph (EEG), electromyograph (EMG), and evoked potentials (EP).

The CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes are disposable electrodes for single patient use. The electrodes are provided non-sterile. The device

consists of 10 electrode assemblies, each consisting of the following: passive Ag/AgCl plated ABS disc permanently adhered to a lead wire, with the leadwire terminated in a touch proof connector (DIN 42 802) for electrical safety.

F. Intended Use / Indications for Use

The single patient EEG Cup Electrode is intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals, for example: Electroencephalograph (EEG) and Nerve potentials signals. The electrodes are for single patient use only.

G. Non-clinical Performance Testing

Non-clinical bench and simulated use testing demonstrate that the CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes are substantially equivalent to the predicate device with regard to intended use/ indication for use, materials, technology, and performance. Design verification demonstrates devices comply with design specifications and applicable sections of ANSI AAMI EC 12, ANSI AAMI ES60601-1, and ANSI AAMI IEC 60601-1-2. Material analysis and testing demonstrate the patient contacting materials are biocompatible and comply with the requirements of ISO 10993-1. Performance testing demonstrates that the performance of the CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes is substantially equivalent to the predicate device.

H. Substantial Equivalence

Comparison of the Intended use and Technological Characteristics with the Predicate Device:

The subject and predicate device share the same intended use: for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. The characteristics of the subject device and the predicate device are summarized in the table below. The subject device is found to be similar to the predicate device with regard to design, function, and technical characteristics.

Attribute	**Subject Device** CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes	**Predicate Device** AMBU NEUROLINE SINGLE PATIENT EEG/EP CUP
Intended Use/Indications for Use	The single patient EEG Cup Electrode is intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals, for example: Electroencephalograph (EEG) and Nerve potentials signals.	The single patient EEG Cup Electrode is intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals, for example: Electroencephalograph (EEG) and Nerve potentials signals. The electrodes are for single patient

Attribute	**Subject Device** CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes	**Predicate Device** AMBU NEUROLINE SINGLE PATIENT EEG/EP CUP
	The electrodes are for single patient use only.	use only.
Classification Regulation	Class II per 21CFR882.1320, cutaneous electrode	Class II per 21CFR882.1320, cutaneous electrode
Product Code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous
Type of Patient Contact	Contacts patient scalp	Contacts patient scalp
Type of Use	Single use, non-sterile, disposable	Single use, non-sterile, disposable
Electrode Cup	Ag/AgCl plated ABS	Ag/AgCl plated ABS
Electrode Cup Dimensions	10 mm	10 mm
Leadwire	PVC insulated tin plated copper	PVC insulated tin plated copper
Leadwire Length	100 cm, 150 cm, 200 cm	100 cm, 150 cm, 200 cm
Connector	DIN 42802 1.5 mm and Touch proof connector	DIN 42802 1.5 mm and Touch proof connector
Compatibility	Can connect to various EEG devices utilizing a DIN socket	Can connect to various EEG devices utilizing a DIN socket
Sterilization	Non-Sterile	Non-Sterile
Biocompatibility	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010

I. Conclusion

The CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes are as safe and effective as the predicate device. The CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes have the same intended use and indications, and similar technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the BRAINSTREAM™ Disposable Deep Cup EEG Electrodes and its predicate raise no new issues of safety or effectiveness. Performance data demonstrate that the CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes are as safe and effective as the predicate device. Thus, the CONMED BRAINSTREAM™ Disposable Deep Cup EEG Electrodes are substantially equivalent.