August 5, 2019

Rhythmlink International, LLC
Gabriel Orsinger
Director of Engineering
1140 First Street South
Columbia, South Carolina 29209

Re: K191225
Trade/Device Name: EEG Electrode Template
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: May 6, 2019
Received: May 7, 2019

Dear Gabriel Orsinger:

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,

for

Vivek Pinto, 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)*

K191225

Device Name

EEG Electrode Template

Indications for Use *(Describe)*

The EEG Electrode Template is intended for use as an accessory to support the placement of electroencephalograph (EEG) electrodes.

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.

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510(k) Summary

807.92(a)(1) Submitter Information	Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209 Phone: 803-252-1222 FDA Registration #: 1067162	
Official Correspondent	Gabriel Orsinger, PhD Director of Engineering Email: gorsinger@rhythmlink.com Phone: 803-365-9664	
Summary Date	August 5, 2019	
807.92(a)(2) Device Identification	**Device Trade Name:** **Common/Classification Name:** **Product Code:** **Classification:** **Classification Panel:**	EEG Electrode Template Cutaneous Electrode GXY 21 CFR 882.1320 Class II Neurology
807.92(a)(3) Predicate Device	K043009 – Brainet Kit	
807.92(a)(4) Device Description	The EEG Electrode Template is intended to be used in medical environments where EEG electrode placement is required. The device provides a workflow solution to support application of EEG electrodes. The EEG Electrode Template is made from elastic webbing to conform to various head shapes and sizes. The device has between 16 to 21 holes in predetermined locations that are arranged by generally referencing the 10-20 Positioning System. The EEG Electrode Template is placed on the patient's head and is oriented with its nasion marker and secured with its chinstrap to support positioning of EEG electrodes. The elasticity of the device enables flexibility to account for various head shapes and sizes and to avoid interference with intracranial pressure monitoring, ventricular drainage, or other separate devices. Identical to the predicate (K043009), the subject device is non-invasive, non-sterile, and for single patient use.	
807.92(a)(5) Intended Use	The EEG Electrode Template is intended for use as an accessory to support the placement of electroencephalograph (EEG) electrodes.	

807.92(a)(6) Technological Characteristics

The technological characteristics of the EEG Electrode Template are identical to the predicate device (K043009), with several minor dimensional and material modifications which have been assessed to be substantially equivalent to the predicate and therefore do not affect the safety or effectiveness of the device (reference Technological Characteristics table, below).

Characteristic	Subject Device: EEG Electrode Template	Predicate Device: Brainet Kit
510(k) Number	K191225	K043009
Manufacturer	Rhythmlink International, LLC	Jordan Neuroscience, Inc.
Device Class	Class II	Class II
Product Code	GXY	GXY GXZ *(different model)*
Regulatory Name	Cutaneous electrode	Cutaneous electrode
Regulation #	21 CFR 882.1320	21 CFR 882.1320
Intended Use	The EEG Electrode Template is intended for use as an accessory to support placement of electroencephalograph (EEG) electrodes.	The Brainet® template is placed on the scalp to support electroencephalograph (EEG) electrode placement.
Single Patient Use	YES – disposable	YES – disposable
Sterilization Method	Non-sterile	Non-sterile
Shelf Life	2 years	N/A – not listed on device
Anatomical Site(s)	Head	Head
Environment usage	Hospital	Hospital
Targeted Procedures	EEG	EEG
Number of Electrode Positions	16 to 21	Up to 21
Electrode Position Identifier	Number and text	Color
Template Materials	Elastic, polyester thread, screen-printed ink, Velcro/Veltex	Elastic, Velcro *(other materials unknown)*
Duration of Use	Short term	Short term
Biocompatible	Yes	Yes

807.92(b)(1) Summary of Non-Clinical Tests

The EEG Electrode Template is substantially equivalent in technology, safety, and effectiveness as the predicate device (K043009), as demonstrated by the test results. Functional performance equivalency was determined by dimensional characterization of the EEG Electrode Template, which demonstrated that all hole-to-hole spacing was within 5 mm of specifications.

In conclusion, all non-clinical performance testing passed predetermined acceptance criteria, demonstrating the EEG Electrode Template is equivalent to the predicate device in functionality, safety, and effectiveness.

807.92(b)(2) Clinical Tests

No Clinical Tests were conducted as referenced in 21 CFR 807.92(b)(2).

807.92(b)(3) Clinical Summary

No Clinical Tests were conducted as referenced in 21 CFR 807.92(b)(3).