February 9, 2021

Rhythmlink International, LLC
Gabriel Orsinger
Vice President of Engineering and R&D
1140 First Street South
Columbia, South Carolina 29209

Re: K203079
Trade/Device Name: MR Conditional Sticky Pad Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: October 12, 2020
Received: October 13, 2020

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203079

Device Name
MR Conditional Sticky Pad Electrode

Indications for Use *(Describe)*
The Rhythmlink MR Conditional Sticky Pad Electrode is intended for use with recording, monitoring, and stimulation equipment in the study of biopotentials such as Electroencephalograph (EEG), Surface Electromyography (EMG), or Nerve Conduction Evoked Potential Signals (EP). This device is non-sterile, single-use only, and may remain on the patient in a MRI environment under specific conditions.

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 Vice President of Engineering and R&D Email: gorsinger@rhythmlink.com Phone: 803-365-9664	
Summary Date	February 02, 2021	
807.92(a)(2) Device Identification	**Device Trade Name:**	MR Conditional Sticky Pad Electrode
	Device 510(k) Number:	K203079
	Common/Classification Name:	Cutaneous Electrode
	Product Code:	GXY
	Classification:	21 CFR 882.1320 Class II
	Classification Panel:	Neurology
807.92(a)(3) Predicate Device	K052188 – Rhythmlink Cutaneous Electrode	
807.92(a)(4) Device Description	The MR Conditional Sticky Pad Electrode is intended to be used in medical environments where quick electrode application is required with minimal skin preparation. The device provides an easy-to-apply solution by combining conductive material used to record biosignals with a hydrogel designed for patient skin adhesion. This combination of materials, with an electrically conductive leadwire designed to fit with patient monitoring and stimulation equipment, provides a fast and easy way to record brain and muscle activity, provide stimulation for evoked potentials, and serve as a ground or reference electrode during monitoring. The MR Conditional Sticky Pad Electrodes have been specifically engineered to remain safely on a patient during MR imaging under the conditions specified in the labeling. Each MR Conditional Sticky Pad Electrode comprises the hydrogel electrode attached to a 240mm long leadwire (MR Conditional Electrode Assembly), which pairs with and connects to a 1.0m to 2.5m long, MR Unsafe Extension Cable. The extension cable provides a quick disconnect function to allow patient to be quickly moved into MR imaging without removing the hydrogel electrodes from the patient. Between 2 and 48 total MR Conditional Electrode Assemblies may remain on the patient during MR imaging in either 1.5T or 3.0T systems. The MR Conditional Electrode Assemblies are marked with yellow “MR Conditional” symbols, and the MR Unsafe Extension Cables are marked in duplicate (one at each end) with red “MR Unsafe” symbols to ensure proper use).	
807.92(a)(5) Indications for Use	The Rhythmlink MR Conditional Sticky Pad Electrode is intended for use with recording, monitoring, and stimulation equipment in the study of biopotentials such as Electroencephalograph (EEG), Surface Electromyography (EMG), or Nerve Conduction Evoked Potential Signals (EP). This device is non-sterile, single-use only, and may remain on the patient in a MRI environment under specific conditions.	
807.92(a)(6) Technological Characteristics	The technological characteristics of the MR Conditional Sticky Pad Electrode are identical to the predicate device (K052188), with a few dimensional and material modifications to enable safe use in the MR environment under specified conditions.These	

modifications include the use of carbon fiber leadwire rather than copper leadwire to connect to the pad electrode, and the addition of an in-line disconnect feature to remove the electrode leadwire from the extension leadwire when in an MR environment. These modifications 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).The test methods were identical to those used to assess the predicate device.

Characteristic	**Subject Device** **MR Conditional Sticky Pad Electrode**	**Predicate Device:** **Cutaneous Pad Electrode**
510(k) Number	K203079	K052188
Manufacturer	Rhythmlink International, LLC	Rhythmlink International, LLC
Device Class	Class II	Class II
Product Code	GXY	GXY
Classification Name	Cutaneous Electrode	Cutaneous Electrode
Device Type	Cutaneous Electrode	Cutaneous Electrode
Regulation #	21 CFR 882.1320	21 CFR 882.1320
Indications For Use	The Rhythmlink MR Conditional Sticky Pad Electrode is intended for use with recording, monitoring, and stimulation equipment in the study of biopotentials such as Electroencephalograph (EEG), Surface Electromyography (EMG), or Nerve Conduction Evoked Potential Signals (EP). This device is non-sterile, single-use only, and may remain on the patient in a MRI environment under specific conditions.	Intended for use with recording, monitoring and stimulation equipment for the purpose of stimulating/ recording of biopotential signals. Electrodes are applied in the study of biopotentials such as Electroencephalograph (EEG), surface Electromyography (EMG), nerve conduction Evoked potential signals (EP). Electrodes are non-invasive as they are applied to the patient's skin using a self-adhesive solid-gel surface. The electrodes are non-sterile and for single patient use only.
Single Patient Use	YES – disposable	YES – disposable
Sterilization Method	Non-sterile	Non-sterile
Shelf Life	2 years	2 years
Anatomical Site(s)	Head and Muscular sites	Head and Muscular sites
Environment usage*	Hospital; MR Conditional at 1.5T or 3.0T	Hospital; Non-MR
Targeted Procedures	EEG, EMG, EP	EEG, EMG, EP
Electrode Material	Non-woven fabric, conductive vinyl, hydrogel	Non-woven fabric, conductive vinyl, hydrogel
Electrode Sizes	Small (15 x 20 mm) Large (20 x 25mm) Ground (35 x 45mm)	Small (15 x 20 mm) Large (20 x 25mm) Ground (35 x 45mm)

Leadwire Material*	PVC-jacketed carbon fiber (MR Conditional Electrode) & Copper (Extension Cable)	PVC-jacketed Copper
Leadwire Length*	240mm (MR Conditional Electrode) + 1.0m to 2.5m Extension Cable	1.0m to 2.5m
Connectors	DIN 42802, 1.5mm Touchproof	DIN 42802, 1.5mm Touchproof
Electrode Application	Applied directly to skin surface	Applied directly to skin surface
Single Patient Use	Yes, disposable	Yes, disposable
Duration of Use	≤ 24 hours	≤ 24 hours
Biocompatible	Yes	Yes

*Any changes from predicate device were evaluated to be substantially equivalent through non-clinical functional performance and MR Safety testing described below.

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

The MR Conditional Sticky Pad Electrode is substantially equivalent in technology, safety, and effectiveness as the predicate device (K052188), as demonstrated by the test results.

Functional performance equivalency was determined by benchtop testing, as follows:

- DC Offset Voltage
- AC Impedance

Additionally, MR Safety evaluation was performed identically to reference device, Rhythmlink MR Conditional Cup & Webb Electrodes (K130287), as follows:

- Numerical Evaluation of SAR Distribution (i.e., worst-case determination)
- Radiofrequency (RF) Induced Heating in 1.5T & 3T systems
- Measurement of Magnetically Induced Displacement Force
- Measurement of Magnetically Induced Torque
- Evaluation of MR Image Artifact

All benchtop performance testing passed predetermined acceptance criteria, demonstrating the MR Conditional Sticky Pad Electrode is substantially 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).

807.92(b)(4) Conclusion

In conclusion, the MR Conditional Sticky Pad Electrode is substantially equivalent to the predicate device. The only changes made to the subject device include (1) a carbon fiber leadwire attached to the electrode, and (2) the addition of an extension leadwire, enabling MR Conditionality. None of these changes raise new questions of safety or effectiveness, and the Submitter has provided applicable performance information to demonstrate that the changes do not adversely impact safety or effectiveness. The Submitter therefore concludes that its MR Conditional Sticky Pad Electrode is substantially equivalent to the Cutaneous Electrode device.