December 1, 2017

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

Re: K172503
Trade/Device Name: MR Conditional Cup Electrode, MR Conditional Webb Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: September 7, 2017
Received: September 11, 2017

Dear Mr. McCoy:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172503

Device Name
MR Conditional Cup Electrode, MR Conditional Webb Electrode

Indications for Use *(Describe)*
The MR Conditional Cup and Webb Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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	Daniel McCoy Vice President Engineering and R&D Email: dmccoy@rhythmlink.com Phone: 803-365-9660
Summary Date	December 1, 2017
807.92(a)(2) Device Identification	**Device Trade Name:** MR Conditional Cup and Webb Electrode **Common/Classification Name:** Cutaneous Electrode **Product Code:** GXY **Classification:** 21 CFR 882.1320 Class II **Classification Panel:** Neurology
807.92(a)(3) Predicate Device	K130287 - MR Conditional Cup and Webb Electrode
807.92(a)(4) Device Description	The fundamental scientific technology of Rhythmlink's MR Conditional Cup and Webb Electrodes is identical to the predicate device. The device consists of ABS molded disk-shaped Cup or Webb style cutaneous electrodes coated with Ag/AgCl. The electrodes are affixed to 18cm long conductive leadwires. Up to 10 leadwires are connected to a multipin touch proof connector to form an electrode array assembly, which is labeled "MR Conditional." Up to 4 electrode arrays can be used simultaneously on a patient. The device design and leadwire length have been engineered for both 1.5T (64MHz) and 3.0T (128 MHz) MRI environments. An extension cable, 1.0 to 3.0m long, is included to attach the electrode array to monitoring equipment. The extension cable is clearly labeled with "MR Unsafe" symbols on both ends, and is NOT intended to be in the MR environment. This enables users to quickly disconnect the MR Unsafe extension cable and leave the MR Conditional electrodes in place on the patient for MRI procedures.
807.92(a)(5) Intended Use	The MR Conditional Cup and Webb Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient 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 Cup and Webb Electrodes are identical to the predicate device (K130287), with a few dimensional and material modifications that have been assessed to be equivalent to the predicate and therefore do not affect the fundamental scientific technology, safety, or effectiveness of the device (reference Substantial Equivalence of Technological Characteristics table, below). The test methods were identical to those used to assess the predicate device.

807.92(b)(1) Summary of Non-Clinical Tests	The MR Conditional Cup and Webb Electrodes exhibit the same fundamental scientific technology, safety, and effectiveness as the predicate device (K130287), as demonstrated by the test results.
	
	The functional performance equivalency was determined by mechanical and electrical benchtop testing, as follows:
	• Tensile testing
	• Continuity testing
	• Signal quality testing
	
	The MR safety and performance equivalency of the MR Conditional Cup and Webb Electrodes were determined using the same test methodology as the predicate device, summarized below:
	• Worst-case device configuration was established through multiple SAR computational simulations
	• The established worst-case configuration of the finished device was tested to the applicable ASTM standards:
	  o RF-Induced Heating
	  o MR Image Artifact
	  o Magnetically Induced Torque
	  o Magnetically Induced Displacement Force
	
	The results of these MR safety and functional tests verified the computational analysis, and determined the MR conditionality and device labeling information for both 1.5 T and 3.0 T MR environments. All MR testing was performed by an accredited MR testing laboratory on behalf of Rhythmlink International, LLC.
	
	In summary, the non-clinical testing concluded that the MR Conditional Cup and Webb Electrodes demonstrated equivalent functionality, safety, and effectiveness as the predicate device.

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).

Substantial Equivalence of Technological Characteristics Table

Characteristic	Modified Device	Predicate Device	Equivalency
Indications for Use	The MR Conditional Cup and Webb Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.	The MR Conditional Cup and Webb Electrodes are intended for use in the recording of the Electroencephalogram (EEG), the evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.	Identical
MR Conditions	Non-clinical testing has demonstrated that the MR Conditional Cup and Webb Electrode array is MR Conditional in configurations of 2 to 40 electrodes, using 1 to 4 arrays. These electrodes can safely remain on a patient during an MR scan meeting the following conditions: • Static magnetic field of 1.5 and 3.0 Tesla • Maximum spatial field gradient of 4,000 gauss/cm [40 T/m] • Maximum MR system reported whole-body averaged specific absorption rate (SAR) of 2 W/kg and whole-head averaged SAR of 3.2 W/kg • Quadrature driven transmit body coil only • Maximum active scan time of 15 minutes	Non-clinical testing has demonstrated that the MR Conditional Cup and Webb Electrode is MR Conditional in configurations of 2 to 48 electrodes. These electrodes can safely remain on a patient during an MR scan under the following conditions: • Static magnetic field of 1.5 or 3.0 Tesla. • Maximum spatial gradient field of 4,000 gauss/cm (40T/m) or less • Maximum whole-body averaged specific absorption rate of 2 W/kg in the Normal Operating Mode • Remove extension cables before entering an MR environment. They are MR Unsafe.	Equivalent
Electrode Material	ABS 20% glass filled, Ag/AgCl coated	ABS 20% glass filled, Ag/AgCl coated	Identical
Electrode Diameter	~10mm	~10mm	Identical
Wire	Conductive cable, PVC coated	Conductive cable, PVC coated	Equivalent
Electrode Cable Length	18cm	10cm	Equivalent
Connector	Touch proof multipin connector(s)	Touch proof single pin connector(s)	Equivalent