July 10, 2019

Rhythmlink International, LLC
Gabriel Orsinger
Manager, Product Development
1140 First Street South
Columbia, South Carolina 29209

Re: K190801
Trade/Device Name: PressOn Electrode Headset
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: June 7, 2019
Received: June 10, 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

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic 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)*
K190801

Device Name
PressOn™ Electrode Headset

Indications for Use *(Describe)*
The PressOn™ Electrode Headset is intended for use in the recording of electroencephalogram (EEG), evoked potential (EP), or as a ground and reference in an EEG or EP recording. The device is provided sterile 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

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	July 9, 2019	
807.92(a)(2) Device Identification	**Device Trade Name:**	PressOn™ Electrode Headset
	Common/Classification Name:	Needle Electrode
	Product Code:	GXZ
	Classification:	21 CFR 882.1350 Class II
	Classification Panel:	Neurology
807.92(a)(3) Predicate Device	K130220 - MR Conditional PressOn Electrode	

807.92(a)(4) Device Description

The PressOn™ Electrode Headset is intended to be used in medical environments where quick EEG electrode application is required. The device provides a workflow solution where the availability of technologists or other specialty-trained EEG staff is limited for applying EEG electrodes.

The headset comprises between 2 to 48 PressOn™ Electrodes, each loaded into individual button applicators, which are positioned in predetermined locations and interconnected by elastic netting, altogether forming the headset. The predetermined electrode positions are arranged by generally referencing the 10-20 Positioning System, but with flexibility to account for various head shapes and sizes and to avoid interference with intracranial pressure monitoring, ventricular drainage, and other separate devices. Like the predicate, the subject device is minimally invasive and does not directly contact neural tissues.

The PressOn™ Electrode Headset is placed on the patient's head and is oriented and secured using a nasion marker and chinstrap. The distal end of the device contains the array of PressOn™ electrodes in predetermined locations that are placed on the scalp by minimal insertion of the micro needles into the epidermis layer of the skin for use during monitoring procedures. The PressOn™ electrodes in the subject device are inserted in an identical fashion as the predicate device (K130220). Minor material and dimensional changes have been made to the original applicator to allow for multiple applicators to be connected to form the headset.

At the proximal end of the subject device is a multipin connector where the electrode leadwires terminate. The multipin connector interfaces with color-coded extension cables (identical to those used in another previously cleared Rhythmlink

device, reference device K172503) that terminate into single pin connectors, which are then connected to monitoring equipment.

The leadwires are constructed of ribbon cable arrays with electrode attachment points at various distances based on the predetermined locations. These features are designed with the intent for quick application by non-neurological based medical personnel with signal quality equivalent to predicate device [K130220].

807.92(a)(5) Intended Use

The PressOn™ Electrode Headset is intended for use in the recording of electroencephalogram (EEG), evoked potential (EP), or as a ground and reference in an EEG or EP recording. The device is provided sterile for single patient use only.

807.92(a)(6) Technological Characteristics

The technological characteristics of the PressOn™ Electrode Headset are identical to the predicate device (K130220), 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). All test methods were identical to those used to assess the predicate device.

Characteristic	Subject Device: PressOn™ Electrode Headset	Predicate Device: MR PressOn™ Electrodes
510(k) Number	K190801	K130220
Manufacturer	Rhythmlink International, LLC	Rhythmlink International, LLC
Device Class	Class II	Class II
Product Code	GXZ	GXZ
Regulatory Name	Subdermal Needle	Subdermal Needle
Device Type	PressOn™ Electrodes	PressOn™ Electrodes
Regulation #	21 CFR 882.1350	21 CFR 882.1350
Intended Use	The PressOn Electrode Headset is intended for use in the recording of Electroencephalogram (EEG), evoked potential (EP), or as a ground and reference in an EEG or EP recording. This device is provided sterile for Single Patient Use Only.	The MR PressOn Electrode is 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 provided sterile for Single Patient Use Only.
Single Patient Use	YES – disposable	YES – disposable
Sterilization Method	Supplied EtO Sterile	Supplied EtO Sterile
Anatomical Site(s)	Head and Muscular sites	Head and Muscular sites
Environment usage	Hospital	Hospital
Targeted Procedures	EEG, EP	EEG, EP
Electrode Material	Nitinol	Nitinol
Size of Electrode	≈ 7 mm	≈ 7 mm
Number of Electrodes per Device	2 to 48	1
Electrode Applicator Dimensions	1.5cm x 2.1cm x 2.1cm	4.5cm x 3.0cm x 1.6cm
Electrode Applicator Materials	ABS, Polycarbonate, Silicone, Stainless Steel	ABS, Polycarbonate

Use of Headset	Yes	No
Electrode Application	Apply positioning headset, then then insert electrodes into the dermis layer with applicators	Insert electrodes into the dermis layer with an applicator
Leadwire	Multi-conductor ribbon cable, PVC-jacketed copper	Single conductor cable, PVC-jacketed copper
Electrode Cable Length	Multiple cables 50 to 500 mm	240mm
Extension Cable Length	Multiple cables 1.0 to 3.0 m, sheathed	Single cable 1.0 to 3.0 m
Connector	1.5mm touchproof DIN 42-802 and multipin touchproof connectors	1.5mm touchproof DIN 42-802 connector
Compatibility with Other Devices	Interfaces with a 1.5mm DIN 42-802 touchproof connector	Interfaces with a 1.5mm DIN 42-802 touchproof connector
MR Safety	MR Unsafe	MR Conditional
Electrical Safety	Connectors comply with IEC 60601-1 (1988) sub clause 56.3(c) per CFR 898.12 (Both the Electrode Cable and the Extension Cable)	Connectors comply with IEC 60601-1 (1988) sub clause 56.3(c) per CFR 898.12 (Both the Electrode Cable and the Extension Cable)
Duration of Use	Electrode: For the length of the procedure, but not more than 30 days. Positioning Headset: used to apply electrodes and then removed.	Electrode: For the length of the procedure, but not more than 30 days
Biocompatible	Yes	Yes

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

The PressOn™ Electrode Headset is substantially equivalent in technology, safety, and effectiveness as the predicate device (K130220), as demonstrated by the test results.

Functional performance equivalency was determined by dimensional characterization, mechanical, and electrical benchtop testing, as follows:

- Electrical Continuity testing of the completed assembly
- Deployment force to eject electrode from applicator and apply to synthetic skin
- Pull force required to remove the electrode from synthetic skin
- Visual assessment of electrode insertion uniformity into synthetic skin
- Dimensional assessment of electrode placement on head phantom

All benchtop performance testing passed predetermined acceptance criteria, demonstrating the PressOn™ Electrode Headset 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).