May 27, 2020

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

Re: K200984
Trade/Device Name: Guardian Needle Electrode
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: April 9, 2020
Received: April 14, 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,

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)*

Device Name
Guardian Needle™ Electrode

Indications for Use *(Describe)*
Rhythmlink International Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephalography (EEG), and Nerve potential signals. The electrodes are sterile and for single patient use.

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 – K200984

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	May 27, 2020	
807.92(a)(2) Device Identification	**Device Trade Name:** **Classification Name:** **Product Code:** **Classification:** **Classification Panel:**	Guardian Needle™ Electrode Needle Electrode GXZ 21 CFR 882.1350 Class II Neurology
807.92(a)(3) Predicate Device	**Device Trade Name:** **Classification Name:** **510(k) Number:** **Product Code:** **Classification:** **Classification Panel:** **Manufacturer:**	Subdermal Needle Electrodes Needle Electrode K022914 GXZ 21 CFR 882.1350 Class II Neurology Rhythmlink International, LLC 1140 First Street South Columbia, SC 29209
807.92(a)(4) Device Description	Guardian Needle™ Electrodes are a sterile, single-use device. The electrodes are applied during the study of biopotentials such as electromyography (EMG), electroencephalography (EEG), nerve conduction and stimulation/response. The electrodes are invasive as they are placed subcutaneously or in contact with nerve or muscle tissue. The needle is housed inside a sheath until application and secured to the patient during use with adhesive tape.	
807.92(a)(5) Intended Use	Rhythmlink International Guardian Needle™ Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephalography (EEG) and Nerve potential signals. The electrodes are sterile and for single patient use only	
807.92(a)(6) Technological Characteristics	The technological characteristics of Guardian Needle™ Electrodes are identical to the predicate device (K022914), with the addition of a needle sheath and adhesive tape, both of which have been assessed to not change the fundamental scientific technology, intended use, performance, or safety and effectiveness of the predicate 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

Guardian Needle™ Electrodes are substantially equivalent in technology, safety, and effectiveness as the predicate device (K022914), as demonstrated by the test results.

The Guardian Needle™ Electrode was assessed by applying the TIR 28:2009 Guidance, from which it was determined that the subject device does not challenge the Submitter's Master Challenge Device and can thus fall under the previously validated EtO sterilization cycle. Reevaluation of the EtO residuals was performed to confirm low levels of EtO and Ethylene Chlorohydrin (ECH) after a 24-hour aeration time below the maximum limits described in ANSI/AAMI/ISO 10993-7:2008/(R) 2012.

The biocompatibility evaluation was conducted within the risk management framework and in compliance with ISO 10993 standards. This biocompatibility evaluation establishes the biological safety for the Guardian Needle™ Electrode with intact skin contact for a limited (≤24 hours) duration

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

- Electrical Continuity
- Adhesion Testing

Benchtop performance testing passed predetermined acceptance criteria, demonstrating Guardian Needle™ Electrodes are 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).

Substantial Equivalence Table

Characteristic	Subject Device: Guardian Needle™ Electrodes	Predicate Device: Subdermal Needle Electrodes	Substantial Equivalence (SE)[1]
510(k) Number	K200984	K022914 Subdermal Needle Electrodes	
Manufacturer	Rhythmlink International, LLC	Rhythmlink International, LLC	SE
Device Class	Class II	Class II	SE
Product Code	GXZ	GXZ	SE
Regulatory Name	Subdermal Needle	Subdermal Needle	SE
Device Type	Subdermal Needle Electrodes	Subdermal Needle Electrodes	SE
Regulation #	21 CFR 882.1350	21 CFR 882.1350	SE
Intended Use	Rhythmlink International Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephalography (EEG), and Nerve potential signals. The electrodes are sterile and for single patient use.	Rhythmlink International Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation equipment for the purpose of recording of biopotential signals. Examples include: Electromyography (EMG), Electroencephalography (EEG), and Nerve potential signals. The electrodes are sterile and for single patient use.	SE
Anatomical Site(s)	Subdermal muscle or nerve tissue	Subdermal muscle or nerve tissue	SE
Environment usage	Hospital	Hospital	SE
Electrode Material	Medical Grade 304VM (vacuum melt) Stainless Steel	Medical Grade 304VM (vacuum melt) Stainless Steel	SE
Electrode Length	7mm to 22 mm	7mm to 22 mm	SE
Electrode Diameter	0.4mm	0.4mm	SE
Leadwire Material	PVC-coated Electrical Wire	PVC-coated Electrical Wire	SE
Leadwire Length	1.0m to 3.0m	1.0m to 3.0m	SE
Connector	1.5mm DIN 42 802 pin touch proof connector	1.5mm DIN 42 802 pin touch proof connector	SE

Characteristic	Subject Device: Guardian Needle™ Electrodes	Predicate Device: Subdermal Needle Electrodes	Substantial Equivalence (SE)[1]
510(k) Number	K200984	K022914 Subdermal Needle Electrodes	
Use of Adhesive Tape	YES	NO	SE; Material change has been validated by testing and does not adversely impact safety or effectiveness
Needle Cover	Thermoplastic polyester elastomer sheath	PVC tube	SE; Material and dimensional change has been validated by testing and does not adversely impact safety or effectiveness
Operation of Applying the Device	Applied subcutaneously to the skin	Applied subcutaneously to the skin	SE
Prescription Use	YES - Inserted by a licensed physician or practitioner	YES - Inserted by a licensed physician or practitioner	SE
Targeted Procedures	IONM, EMG, EP, EEG	IONM, EMG, EP, EEG	SE
Compatibility with other devices	Neurophysiology Monitors with a 1.5mm DIN 42 802 pin touch proof connector	Neurophysiology Monitors with a 1.5mm DIN 42 802 pin touch proof connector	SE
Packaging	24 electrodes sealed in a Tyvek pouch and placed inside a sealed, labeled box	24 electrodes sealed in a Tyvek pouch and placed inside a sealed, labeled box	SE
Sterilization Method	Supplied EtO Sterile	Supplied EtO Sterile	SE
Single Patient Use	YES – disposable	YES - disposable	SE
Electrical Safety	Connectors comply with IEC 60601-1 (1988) sub clause 56.3(c) per CFR 898.12	Connectors comply with IEC 60601-1 (1988) sub clause 56.3(c) per CFR 898.12	SE

Characteristic	Subject Device: Guardian Needle™ Electrodes	Predicate Device: Subdermal Needle Electrodes	Substantial Equivalence (SE)[1]
510(k) Number	K200984	K022914 Subdermal Needle Electrodes	
Mechanical Safety	Leadwires are soldered to electrode using Tin/Silver solder and covered with heat shrink	Leadwires are soldered to electrode using Tin/Silver solder and covered with heat shrink	SE
Duration of use	≤24 hours	≤24 hours	SE
Standards	• IEC 60601-1-1: 1988/a1: 1991/A2 :1995 § 56.3(c) per CFR 898.12 • DIN 42802 • ISO 14971 • ISO 15223-1	• IEC 60601-1-1: 1988/a1: 1991/A2 :1995 § 56.3(c) per CFR 898.12 • DIN 42802 • ISO 14971 • ISO 15223-1	SE
Biocompatible	Yes	Yes	SE

[1]Only differences are indicated in this column.