DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 3, 2015

Rochester Electro-Medical, Inc.
c/o Wayne Glover
TechniReg, Inc.
19404 Pine Valley Drive
Odessa, FL 33556

Re: K142159
Trade/Device Name: Disposable Pre-gelled Surface Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 28, 2015
Received: May 5, 2015

Dear Mr. Glover,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142159

Device Name
Disposable Pre-gelled Surface Electrode

Indications for Use *(Describe)*
The Disposable Pre-gelled Surface Electrodes are intended for recording/stimulation and monitoring of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potential (EP) signals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Summary Date: August 1, 2014

Manufacturer: Rochester Electro-Medical, Inc.
4212 Cypress Gulch Drive
Lutz, FL 33559

Telephone: (813) 963-2933

Establishment Registration No.: 2126558

Contact Person: Mark C. Berkins
Vice President
Phone: (813) 963-2933, Extension 221
Fax: (800) 545-0845

Trade Name: Disposable Pre-gelled Surface Electrode[1]

[1] This submission is intended to be filed as a Cutaneous Electrode (i.e. Common Name) although referenced by the Trade Name throughout this submission.

Common Name: Cutaneous Electrode

Classification Name: 882.1320 Cutaneous Electrode, Class II (performance standards)

Product Code: GXY

Equivalence / Predicate Device: Friendship Pre-gelled Ag/AgCl Surface Electrodes, 510(k) Number K110289

Description: A conductive solid gel electrode consisting of a conductive adhesive gel, a silver/silver chloride plated eyelet, an adhesive cloth substrate, label, lead wire with a 0.60" diameter touch-proof female socket per DIN 42802 and polystyrene release liner. These are available in various lead lengths, lead configurations, electrode styles/sizes, and wire colors.

Intended Use: The Rochester Electro-Medical Disposable Pre-gelled Surface Electrodes are 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) and 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 use only.

The surface electrodes are placed cutaneously by a certified physician or a trained clinician or technologist by the order of a physician.

Technical Comparison:

The Rochester Disposable Adhesive Surface Electrodes are technologically equivalent to the predicate device, K110289 Cutaneous Electrode manufactured by Xian Friendship Medical.

Physical and electrical characteristics evaluated during bench testing and in the comparison chart of this submission demonstrate that the design, materials, chemical composition, packaging, intended use, electrical performance and other characteristics of the subject device are comparable to those of the predicate device.

Bench testing included electrode impedance measurements of the subject device and the predicate using a 1kHz source and a Digital Multimeter, a method similar to that used in K010431. Additionally gel uniformity was inspected. Details of this testing and performance criteria are included in section 18 of this submission, Performance Testing – Bench.

Biocompatibility:

The contact material is Tyco hydrogel RG-63 with slight proprietary variations and has been previously tested for material safety and biocompatibility to:

- Cytotoxicity study – ISO 10993-5
- Skin irritation study – ISO 10993-10
- Skin sensitization study – ISO 10993-10

There were no changes to the formulation for the new intended use.

Shelf Life:

18 Months in unopened pouch.

Conclusions:

The Rochester Electro-Medical Disposable Pre-gelled Surface Electrodes are substantially equivalent to the predicate device, Xian Friendship Medical Electronics Co., Ltd.

There are no new concerns regarding safety or effectiveness.