November 13, 2017

Embla Systems
Sanjay Mehta
Senior Manager, Quality Assurance & Regulatory Affairs
1 Hines Road, Suite 202
Kanata, ON, CA, K2K 3C7

Re: K172703
Trade/Device Name: Disposable Snap Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 31, 2017
Received: September 7, 2017

Dear Sanjay Mehta:

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 (DICE) 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 (DICE) 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,

Michael J. Hoffmann -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)*
K172703

Device Name
Disposable Snap Electrode

Indications for Use *(Describe)*
The Disposable Snap Electrodes are intended to be used with compatible 1.5mm touchproof button snap cables for transferring surface biopotential signals to use during sleep studies, EEG, EMG, and recording evoked potential signals from a cutaneous location. For use on Adults.

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.

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"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 summary is provided to support the 510(k) pre-market notification for the Disposable Snap Electrode.

Company Name: Embla Systems
1 Hines Road, Suite 202
Kanata, ON, CA, K2K 3C7

Company Contact: Mr. Sanjay Mehta
Senior Manager, Quality Assurance & Regulatory Affairs
Phone: (905) 287-5055
Email: Sanjay.Mehta@natus.com

Date Summary Prepared: November 3, 2017

Trade Name:	Disposable Snap Electrode
Common Name:	Cutaneous Electrode
Classification Name:	21 CFR 882.1320 Cutaneous Electrode Product Code: GXY
Predicate Devices:	K142159 Disposable Pre-gelled Surface Electrode Rochester Electro-Medical, Inc.
	K021537 Multipurpose Neuroplus Electrode Vermont Medical, Inc.

Product Description

The Disposable Snap Electrode is a cutaneous applied electrode supporting interface of biopotential signals to user equipment. The Snap Electrode has a 4 mm snap contact that can connect with commercially available snap electrode lead wires.

Intended Use of the Device

The Disposable Snap Electrodes are intended to be used with compatible 1.5mm touchproof button snap cables for transferring surface biopotential signals to use during sleep studies, EEG, EMG, and recording evoked potential signals from a cutaneous location. For use on Adults.

Summary of Technological Characteristics

The following table provides a side-by-side comparison of the Disposable Snap Electrode to the predicate devices applied to support this pre-market notification.

Table 1: Substantial Equivalence Technical Characteristics			
Feature	**Disposable Snap Electrodes Under Review**	**Vermont Med., Inc. Multipurpose Neuroplus Electrode, (Predicate K021537)**	**Rochester Electro-Medical, Inc. Disposable Pre-gelled Surface Electrode (Predicate K142159)**
Intended Use	A cutaneous electrode applied directly to a patient's skin either to record physiological signals.	A cutaneous electrode applied directly to a patient's skin either to record physiological signals.	A cutaneous electrode applied directly to a patient's skin either to record physiological signals and/or to apply electrical stimulation.
Indications for Use	The Disposable Snap Electrodes are intended to be used with compatible 1.5mm touch proof button snap cables for transferring surface biopotential signals to use during sleep studies, EEG, EMG, and recording evoked potential signals from a cutaneous location. For use on Adults.	The Vermed A10005 electrode is designed to measure muscle activity from the surface of the skin. The A10005 can be used for Sleep Studies, surface EMG, NCS and EP. The A10005 electrode is provided in a NON-STERILE format only, and should be used on the surface of the skin.	The Disposable Pre-gelled Surface Electrodes are intended for recording/stimulation and monitoring of Electromyography (EMG), Electroencephalograph (EEG) and Evoked Potential (EP) signals.
Environment of Use	Hospitals, clinics and home.	Hospitals, clinics and home.	Hospitals, clinics and home.
Single patient use, disposable	Yes	Yes	Yes
Duration of use	Duration of a sleep study, anticipated to be up to 10 hours	Duration of clinical uses, anticipated to be ≤ 24 hours.	Duration of clinical uses, anticipated to be ≤ 24 hours.
Patient applied location	Cutaneous	Cutaneous	Cutaneous
Overall diameter	1.9 inches	0.875 to 1.375 inches	Unknown
Pre-gelled electrode conductive media	Yes	Yes	Yes
Electrode contact material	Silver, Silver Chloride (Ag/AgCl)	Ag/AgCl	Ag/AgCl
Patient contact material	Adhesive Electrode conductive media	Adhesive Electrode conductive media	Adhesive Electrode conductive media
Sterility	Supplied non-sterile	Supplied non-sterile	Supplied non-sterile
Pre-attached lead wires	No	No	Yes
Snap lead wire compatible	Yes	Yes	Not applicable, pre-wired lead wire

Table 1: Substantial Equivalence Technical Characteristics			
Feature	**Disposable Snap Electrodes Under Review**	**Vermont Med., Inc. Multipurpose Neuroplus Electrode, (Predicate K021537)**	**Rochester Electro-Medical, Inc. Disposable Pre-gelled Surface Electrode (Predicate K142159)**
Shelf Life	18 months	18 months	Unknown
Connection to user's equipment	Yes	Yes	Yes

As indicated in Table 1, the Disposable Snap Electrode under review is substantially equivalent to the predicate devices. The electrode under review has a larger overall diameter than the predicate device. Cutaneous electrodes are selected and applied by medical professionals. The medical professional applies the electrode to a cutaneous location that can accommodate this diameter.

Performance Tests to Demonstrate Substantial Equivalency

To establish the technical equivalency of the Disposable Snap Electrode, evaluations were conducted to confirm compliance with performance requirements, including:

Test	**Summary of Requirement**	**Result**
Performance requirements	Essential performance for: AC Impedance, DC offset, Combined offset instability, Combined offset instability test and Bias current	Pass
Adhesion	Retains adhesion to cutaneous location for minimum of 10 hours.	Pass
Dimensions	1.9 inches +/- 10%	Pass
Lead wire compatibility	Compatible with snap electrode lead wires.	Pass

Standards Applied

In compliance with ANSI/AAMI/ISO 10993-1: 2009/(R)2013, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, the biocompatibility evaluations of the skin contacting Solid Hydrogel and adhesive materials of the Disposable Snap Electrode were performed by the suppliers. The following biocompatibility evaluation reports for the Solid Hydrogel were provided by the supplier:

- Cytotoxicity,
- Sensitization, and
- Irritation by Primary Skin Irritation Test.

The skin contact tape adhesive supplier provided a summary of the biocompatibility test results for the adhesive. The adhesive supplier indicates the following biocompatibility tests were performed:

- Cytotoxicity,
- Sensitization, and
- Primary Irritation.

Conclusion

The Disposable Snap Electrode meets performance requirements. The intended use and technology of the Disposable Snap Electrode are the same as the predicate devices. The Disposable Snap Electrode is substantially equivalent to the predicate devices.