January 3, 2023

South Dakota Partners
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K223775
Trade/Device Name: EZ-STIK Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: December 14, 2022
Received: December 16, 2022

Dear Dave Yungvirt:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223775

Device Name
EZ-STIK Electrodes

Indications for Use *(Describe)*
The EZ-STIK Electrodes are intended for use as a disposable, reusable, conductive adhesive interface between the patient's skin and the electrical stimulator. The EZ-STIK Electrodes are designed and intended to be used with marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscle Stimulation), IF (Inferential), or PGF (Pulsed Galvanic Stimulation). The electrode is for OTC (Over-the-Counter) or Prescription 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.

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205 Hwy 22 E
Clear Lake, SD 57226
www.sdpartnersinc.com
T: (800) 626-3098

510(k) Summary

Contact Details — 21 CFR 807.92(a)(1)

Applicant Name	South Dakota Partners
Applicant Address	205 Hwy 22 E Clear Lake, SD 57226 United States
Applicant Contact	Mike Plunkett
Applicant Contact Email	Mike.plunkett@sdpartnersinc.com
Correspondent Name	Simbex
Correspondent Address	10 Water St Suite 410 Lebanon, NH 03766 United States
Correspondent Contact Telephone	504-432-8171
Correspondent Contact	Amaris Ajamil, PhD, RAC
Correspondent Contact Email	aajamil@simbex.com

Device Name — 21 CFR 807.92(a)(2)

Device Trade Name	EZ-STIK Electrodes
Common Name	EZ-STIK Electrodes
Classification Name	Electrode, Cutaneous
Regulation Number	21 CR 882.1320
Product Code	GXY

Legally Marketed Predicate Devices — 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
K050469	EZ-STIK Electrodes	GXY
K160138	Adhesive Electrodes	GXY

Device Description Summary — 21 CFR 807.92(a)(4)

EZ-STIK Electrodes have a basic 3-layer construction of non-woven polyester material or soft PVC foam, carbon film coated with silver and conductive hydrogel. EZ-STIK Electrodes are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application.

First layer: Insulating backing material- non-woven polyester material or soft PVC foam coated with biocompatible medical adhesive tape

Second layer: Conductive carbon-carbon film or Carbon film/Carbon film coated with silver film

Third layer: Biocompatible self-adhesive conductive hydrogel

The electrodes are designed for single-patient/multiple application use. Because of the biocompatible conductive hydrogel's adhesive nature, no securing materials are required to secure the device to the

205 Hwy 22 E
Clear Lake, SD 57226
www.sdpartnersinc.com
T: (800) 626-3098

patient's skin. The electrode is connected to the electrical stimulator by lead wire, with a standard .080" female socket connector. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages. Wire assembly complies with FDA performance standard 21 CFR Part 898.

Intended Use/Indications For Use **21 CFR 807.92(a)(5)**

The EZ-STIK Electrodes are intended for use as a disposable, reusable, conductive adhesive interface between the patient's skin and the electrical stimulator. The EZ-STIK Electrodes are designed and intended to be used with marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscle Stimulation), IF (Inferential), or PGF (Pulsed Galvanic Stimulation). The electrode is for OTC (Over-the-Counter) or Prescription Use.

Indications For Use Comparison **21 CFR 807.92(a)(5)**

The subject and the predicate devices (K050469 and K160138) have the same intended use. The subject and predicate devices are cutaneous electrodes intended for use as a disposable, reusable, conductive adhesive interface between the patient's skin and the electrical stimulator. The subject and predicate devices are intended to be single patient reusable. The subject EZ-STIK electrode and predicate Adhesive Electrode (K160138) are indicated as OTC and prescription devices intended for use by healthcare professionals and lay persons, whereas the predicate EZ-STIK Electrode is indicated for prescription use only. As such, the subject EZ-STIK Electrode is substantially equivalent to the predicate device Adhesive Electrode with respect to intended use and indications for use.

Technological Comparison **21 CFR 807.92(a)(6)**

At a high level, the subject and predicate devices (K050469 and K160138) are based on the same technological elements:
- Use of three layers (insulating material, conductive carbon film with or without silver layer, biocompatible adhesive hydrogel)
- Use of Leadwire for electrical connections
- Provided non-sterile
- Greater than 6lbf pull strength

The following technological differences exist between the subject and predicate devices:
- Use of different hydrogel material

Non-Clinical and/or Clinical Tests Summary & Conclusions **21 CFR 807.92(b)**

The following performance data were provided in support of the substantial equivalence determination.

The biocompatibility evaluation for the EZ-STIK Electrodes was conducted in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:
Cytotoxicity, Sensitization, and Irritation. The EZ-STIK Electrode is considered direct tissue contacting for a duration of less than 24 hours.

South Dakota Partners
A Salona Global Medical Device Company

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Clear Lake, SD 57226
www.sdpartnersinc.com
T: (800) 626-3098

To verify the safety and performance of the EZ-STIK Electrode, the subject device was tested in the same method as the previously cleared EZ-STIK Electrode (K050469), including electrical performance test, pull and peel test, and shelf-life test.

No clinical data were necessary for this submission.

For all electrical and physical performance tests conducted, the subject device results were shown to be within the acceptance range generated from direct testing of predicate device. The test results and information contained in this submission demonstrate that any differences in technological characteristics do not raise any new questions of safety or effectiveness. Thus, the subject EZ-STIK Electrodes are substantially equivalent to the predicate EZ-STIK Electrodes.