October 30, 2016

Medico Electrodes International Ltd.
Amit Seth
Vice President
Plot 142A/11, 12, 27, 28 & 29, Noida Special Economic Zone
Noida, Uttar Pradesh 201305 India

Re: K161282
Trade/Device Name: FlexStim Neurostimulation Electrodes
Model Numbers: 5050ROC1S, 5050ROC1W, 5050ROC2S,
5050ROC2W, 5050SQC1S, 5050SQC1W, 5050SQC2S, 5050SQC2W
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: September 8, 2016
Received: September 28, 2016

Dear Amit Seth:

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” (21CFR 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,

Michael J. Hoffmann -A

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
510(k) Number (if known)
K161282

Device Name
FlexStim Neurostimulation Electrodes
Model Numbers: 5050ROC1S, 5050ROC1W, 5050ROC2S, 5050ROC2W, 5050SQC1S, 5050SQC1W, 5050SQC2S, 5050SQC2W

Indications for Use
Reusable, self-adhering neurostimulation electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

Type of Use (Select one or both, as applicable)

- [X] Prescription Use (Part 21 CFR 801 Subpart D)
- [X] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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
(As required by 21 CFR 807.92)

I. SUBMITTER

Medico Electrodes International Ltd.
Plot 142A/11, 12, 27, 28 & 29,
Noida Special Economic Zone, Noida – 201305,
Uttar Pradesh, India

Phone: 91-120-3042984
Fax: 91-120-3042986

Contact Person: Amit Seth
Date Prepared: Oct 28, 2016

II. DEVICE

Name of Device: FlexStim Neurostimulation Electrodes
Model Numbers:
5050ROC1S
5050ROC1W
5050ROC2S
5050ROC2W
5050SQC1S
5050SQC1W
5050SQC2S
5050SQC2W
Common or Usual Name: Neurostimulation Electrodes
Classification Name: Cutaneous electrode (21 CFR 882.1320)
Regulatory Class: II
Product Code: GXY

III. PREDICATE DEVICE

PROTENS Reusable Stimulating Electrodes, K142099 (Predicate Device 1)
Reusable Stimulating Electrodes, K111270 (Predicate Device 2)

These predicate devices had not been subject to a design-related recall.
No reference devices were used in these submissions.
IV. DEVICE DESCRIPTION

1. Device Identification

The FlexStim Neurostimulation Electrode is used as a transcutaneous electrical nerve stimulation electrode in conjunction with an electrical stimulator for TENS or EMS and available in backing materials such as, non-woven cloth and PE foam, conductive carbon film (low impedance and standard impedance) with lead wire and snap connection configurations.

2. Device Characteristics

- Software: Not Applicable
- Biologics: Not Applicable
- Drugs: Not Applicable
- Any patient-contacting materials: Conductive hydrogel
- Coatings: Not Applicable
- Additives: Not Applicable
- The electrodes are designed for single patient/multiple application use
- The device is not a sterile product, therefore sterilization is not required

3. Environment of Use:

- Healthcare facility/hospital
- Home

4. Description of the Device

The device functions as a passive device by carrying an electrical signal from a neurostimulation device through the device cable and electrode lead wire or snap button to the user’s skin.
5. Materials of Use

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Component</th>
<th>Description/Material of Construction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Backing material(s)</td>
<td>Non-woven cloth/PE foam</td>
</tr>
<tr>
<td>2</td>
<td>Lead wire having insulation on female connector</td>
<td>Wire length: 114.3 mm or 4.5&quot; (104.3 mm or 4.1&quot; – 124.3 mm or 4.9&quot;)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Din size: 2.0 mm</td>
</tr>
<tr>
<td>3</td>
<td>Stud/Snap (for electrodes without lead wire)</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>4</td>
<td>Sensor/Eyelet (for electrodes without lead wire)</td>
<td>Glass filled ABS with Ag/AgCl coating</td>
</tr>
<tr>
<td>5</td>
<td>Carbon film</td>
<td>Conductive carbon film (low impedance and standard impedance)</td>
</tr>
<tr>
<td>6</td>
<td>Gel</td>
<td>Conductive hydrogel</td>
</tr>
<tr>
<td>7</td>
<td>Release liner</td>
<td>PET i.e., Polyethylene terephthalate</td>
</tr>
</tbody>
</table>

V. INDICATIONS FOR USE

Reusable, self-adhering Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user's skin and a neurostimulation device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The FlexStim Neurostimulation Electrodes exhibit technological characteristics that are substantially equivalent to those of the predicate devices, as determined by both component usage and physical testing.

The Substantial Equivalence summary is described below:
<table>
<thead>
<tr>
<th>S. No.</th>
<th>Areas of Comparison</th>
<th>Subject Device</th>
<th>Predicate Device 1</th>
<th>Predicate Device 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>FlexStim Neurostimulation Electrodes (Manufactured by Medico Electrodes International Ltd., India)</td>
<td>PROTENS Reusable Stimulating Electrodes (K142099) (Manufactured by Bio Protech Inc., Korea)</td>
<td>Bio Protech Reusable Stimulating Electrodes (K111270) (Manufactured by Bio Protech Inc., Korea)</td>
</tr>
<tr>
<td>1</td>
<td>Intended Use / Indications for Use</td>
<td>Reusable, self-adhering, Neurostimulation Electrodes are indicated for use with transcutaneous electrical stimulation devices. Some common types of transcutaneous stimulation devices include, but are not limited to, transepithelial nerve stimulation (TENS) and electrical muscle stimulation (EMS) devices. Transcutaneous Neurostimulation Electrodes are passive devices serving as an interface between a user’s skin and a neurostimulation device.</td>
<td>PROTENS reusable, self-adhering, over-the-counter Cutaneous electrodes are indicated for use with electrical stimulation device. Some common types of electrical stimulation device include, but are not limited to, transcutaneous nerve stimulation (TENS), electrical muscle stimulation (EMS) device, Neuromuscular Electrical Stimulation (NMES/FES) device and Microcurrent electrical nerve stimulation (MENS), Interferential Stimulation (IF). Cutaneous electrodes are passive devices serving as an interface between a user’s skin and an electrical stimulation</td>
<td>Bio Protech Reusable Stimulating electrodes are intended to be used to apply electrical stimulation current to the patient’s skin or to record physiological signals. Electrical stimulation current applications of these electrodes are: a) Transcutaneous Electrical Nerve Stimulation (TENS) for pain relief b) Electrical muscle stimulation (EMS) c) Functional electrical stimulation (FES) d) Microcurrent electrical nerve stimulation (MENS) e) Interferential stimulation (IF) f) Neuromuscular electrical stimulation (NMES)</td>
</tr>
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<td>Reusable Stimulating Electrodes (K111270) (Manufactured by Bio Protech Inc., Korea)</td>
</tr>
<tr>
<td>2</td>
<td>Target population</td>
<td>Adults</td>
<td>Adults</td>
<td>Adults</td>
</tr>
<tr>
<td>3</td>
<td>Anatomical site</td>
<td>Intact skin (refer IFU)</td>
<td>Intact skin (refer IFU)</td>
<td>Intact skin (refer IFU)</td>
</tr>
<tr>
<td>4</td>
<td>Where used</td>
<td>Hospital, clinic and home use environment</td>
<td>Hospital, clinic and home use environment</td>
<td>Hospital, clinic and home use environment</td>
</tr>
<tr>
<td>5</td>
<td>Design</td>
<td>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a lead wire or snap button; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient’s skin.</td>
<td>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a lead wire; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient’s skin.</td>
<td>Cutaneous electrode which conducts an electrical signal from a neurostimulation device through a lead wire; which is dispersed from the wire across a conductive surface; then transmitted through the conductive adhesive gel to the surface of the patient’s skin.</td>
</tr>
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</table>
| 6     | Materials           | Basic components:  
- Backing material (Non-woven cloth/PE foam)  
- Lead wire and snap connection configurations | Basic components:  
- Backing material (Non-woven cloth/PE Foam/Tricot)  
- Lead wire and snap connection | Basic components:  
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- Lead wire and snap connection configurations |
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</tbody>
</table>
| 7     | Performance         | - Conductive carbon film  
- Hydrogel  
- PET liner | configurations  
- Conductive carbon/silver film  
- Hydrogel  
- Transparent PET liner | - Conductive carbon/silver film  
- Hydrogel  
- Transparent PET liner |
<p>|       |                     | Based on successful biocompatibility testing of the skin contacting conductive hydrogel, impedance testing of the product, electrical performance of the insulated lead wire components, adhesive performance and stability, the FlexStim Neurostimulation Electrodes are safe and effective when used as an interface between a user’s skin and an approved neurostimulation devices. | Based on successful biocompatibility testing of the skin contacting conductive hydrogel, impedance testing of the product, electrical performance of the insulated lead wire components and adhesive performance, the PROTENS Reusable Stimulating Electrodes are safe and effective when used as an interface between a user’s skin and an approved neurostimulation devices. | Based on successful biocompatibility testing of the skin contacting conductive hydrogel, impedance testing of the product, electrical performance of the insulated lead wire components and adhesive performance, the Reusable Stimulating Electrodes are safe and effective when used as an interface between a user’s skin and an approved neurostimulation devices. |
| 8     | Biocompatibility    | The skin-contacting Hydrogel | Hydrogel | Hydrogel |</p>
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<tr>
<td></td>
<td>material i.e., hydrogel was found to be biocompatible for its intended use as per ISO 10993-1 standard.</td>
<td>Bio- Compatible</td>
<td>Bio-Compatible</td>
<td>Bio- Compatible</td>
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<td></td>
<td></td>
<td>High Adhesion</td>
<td>High Adhesion</td>
<td>High Adhesion</td>
</tr>
<tr>
<td>9</td>
<td>Differences</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Intended Use</td>
<td>Intended to be used to apply electrical stimulation current to the patient’s skin</td>
<td>Intended to be used to apply electrical stimulation current to the patient’s skin</td>
<td>Intended to be used to apply electrical stimulation current to the patient’s skin or to record physiological signals.</td>
</tr>
<tr>
<td></td>
<td>Materials</td>
<td>FlexStim Neurostimulation Electrodes use Non-woven cloth and PE foam as the backing materials</td>
<td>Reusable Stimulating Electrodes use backing materials such as Non-woven cloth, PE Foam, Tricot</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Conductive carbon film</td>
<td>• Conductive film – carbon film or silver film</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method of sale and supply</td>
<td>We claim that these electrodes can be sold as OTC (21 CFR 801 Subpart C) as well as Prescription (21 CFR 801 Subpart D) medical devices.</td>
<td>The devices are currently being sold as OTC medical devices.</td>
<td>The devices are currently being sold as Prescription medical devices.</td>
</tr>
</tbody>
</table>
VII. PERFORMANCE DATA

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

1. Biocompatibility

The biocompatibility evaluation for the FlexStim Neurostimulation Electrodes was conducted in accordance with the 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
- Irritation

The skin-contacting material i.e., conductive hydrogel was found to be biocompatible for its intended use.

2. Electrical Performance

Impedance testing of the product was performed using the Surface Electrode Analysis Meter (SEAM 10). The equipment has been designed by CALM Technologies Inc., Canada to test the impedance of Neurostimulation Electrodes under a wide range of current pulse inputs, thereby assuring that the electrode has conductive properties appropriate to the device’s intended use.

As per the Certificate of Compliance (CoC) received from the vendor of lead wire, the lead wire assembly is in compliance with the requirements of FDA performance standard 21 CFR Part 898 by testing under IEC 60601-1, sub-clause 56.3 (c).

3. Adhesive Performance

In order to assure that the electrode’s adhesive performance is substantially equivalent to the predicate devices, the Peel Test was performed as per the International Standard Afera 5001. Based on the results, it was concluded that the design of the electrode ensures that it will adhere to the patient’s skin for a duration of use compatible with the intended use of the device.
4. Stability

- FlexStim electrode samples had undergone an accelerated shelf-life study when kept at 40°C ± 2°C and relative humidity of 75% ± 5% in a Calibrated Stability Chamber (SC-01) and tested at 0, 3 & 6 Months to monitor the critical parameters of finished device such as impedance and peel adhesion.

- Apart from samples kept at accelerated ageing temperature, in parallel, samples were also kept at ambient temperature (25°C ± 2°C and relative humidity of 60% ± 5%) and tested for impedance & peel adhesion to demonstrate performance of the hydrogel for up to 11 months.

- As per the accelerated and real time stability study results, it is concluded that the product passes electrical (impedance testing) and adhesive performance test. The product is suitable for use up to 24 months when stored at 5°C - 30°C. This further implies that the hydrogel is stable and resist physical and chemical breakdown as a result of conducting electrical current and extended periods of storage over a range of environmental conditions.

VIII. CONCLUSIONS

Medico Electrodes International Ltd., India considers the FlexStim Neurostimulation Electrodes to be as safe and effective as the predicate devices PROTENS Reusable Stimulating Electrodes (K142099) and Reusable Stimulating Electrodes (K111270) as the subject device has identical indications for use, technological characteristics (including design and materials) and performance specifications as compared to the predicate devices already being legally marketed in the United States. Thus, the device is substantially equivalent to the predicates and any difference between the devices do not pose new questions of safety and effectiveness.