K130816

Section 5 – 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.87(h) and 21 CFR 807.92.

JUN 21 2013

Submitter Information:
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Date Summary Prepared: 06/20/13

Product Name & Classification:
Trade Name: InterX Sterile Self-Adhesive Dual Electrode (ISSDE)
Classification Name: Cutaneous Electrodes
Classification Regulation: 21CFR 882.1320
Classification Code: GXY
Classification Panel: Neurology

Predicate Device Information:

1. Device Name: Superior StarBurst TENS/NMES/FES Stimulating Electrodes
   Manufacturer: Covidien, LP
   510(k) Reference: K083350

2. Device Name: Sterile Post Operative Electrodes Self-Adhering
   Manufacturer: Covidien
   510(k) Reference: K900997 (510(k) holder: Katecho, Inc.)

3. Device Name: Reusable and Self-Adhering TENS.NMES.FES Stimulating Electrodes (Classic # 2404)
   Manufacturer: Covidien
   510(k) Reference: K900519 (510(k) holder: Classic Medical Products, Inc.)

Product Description:
The Proposed ISSDE is a flexible, sterile laminate composed of a top cover, a reinforcement film, dual conductive members with printed silver, biocompatible conductive hydrogel, a release liner which protects the hydrogel before use and during storage and a 2-conductor cable secured between the reinforcement film and the conductive members. The electrodes do not contain active electronics, software or firmware. The cable connects the dual-electrode to the InterX electrical stimulation device. A single finished dual-electrode is placed into a protective pouch

which is then sealed, gamma sterilized and boxed for shipment. The Proposed ISSDE is designed for single-patient/multiple application use.

Intended Use:
ISSDE is indicated for use with InterX Transcutaneous Electrical Nerve Stimulator, previously cleared by FDA (K042912). The ISSDE provides the conductive interface between the InterX stimulation device and the patient's skin. The ISSDE is not made with natural rubber latex, is reusable (single patient only), and is provided packaged and labeled as a sterile device, for single patient use. As a sterile device, the ISSDE can be applied to patients in a sterile post-operative healthcare setting. NRG only guarantees sterility for the first application, however, ISSDE can be repositioned and reapplied (single patient only) as a non-sterile device for subsequent applications. Refer to the labeling for reuse instructions.

Indications for Use:
ISSDE is indicated for use with InterX Transcutaneous Electrical Nerve Stimulator. The ISSDE provides the conductive interface between the InterX stimulation device and the patient's skin. The ISSDE is not made with natural rubber latex, is reusable (single patient only), and is provided packaged and labeled as a sterile device, for single patient use.

Technological Characteristics:
The Proposed ISSDE exhibits identical technological characteristics as compared to the following predicates:

- Covidien's Superior StarBurst TENS/NMES/FES Stimulating Electrodes (K083350)
- Covidien's Sterile Post Operative Electrodes Self-Adhering (K900997)
- Covidien's Reusable and Self-Adhering TENS.NMES.FES Stimulating Electrodes (Classic # 2404) (K900519)

The electrode is composed of a top cover, a reinforcement film, dual conductive members with printed silver, biocompatible conductive hydrogel, a release liner which protects the hydrogel before use and during storage and a 2-conductor cable secured between the reinforcement film and the conductive members.

Bench Testing:
The InterX Sterile Self-Adhesive Dual Electrode (ISSDE) and the predicate devices were tested per protocol in accordance with the FDA's "Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Cutaneous Electrode (April 5, 2010)". ISSDE gel electrodes were sterilized to a very high radiation level (greater than 40 kGy) to create a worst case scenario for gel degradation. Electrical performance of the ISSDE was tested for uniform energy distribution along the length of each electrode. Comparison of energy distribution of the ISSDE electrodes were made to FDA cleared predicate gel electrode devices. Another performance factor of particular interest was impedance, which was measured across the total surface area of each ISSDE gel electrode. The results from the tests performed provide evidence that design verification per 21CFR-820.30(g) was met.

ISSDE complies with the applicable requirements of the following standards:

No.	Standard Reference & Revision	Title	Deviations
1	ISO 15223-1(Second Edition)	Medical Devices – Symbols to be used with medical device labels,	None

		labeling, and information to be supplied – Part 1: General requirements	
2	ISO 10993-1:1997	Biological evaluation of medical devices – Part 1: Evaluation & Testing	None
3	ISO 10993-5:1999	Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity	None
4	ISO 10993-10:1996	Biological evaluation of medical devices – Part 10: Tests for Irritation and Delayed-type Hypersensitivity	None
5	ISO 11607-1:2006 (R) 2010	Packaging for terminally sterilized medical device- Part 1: Requirements for materials, sterile barrier systems and packaging systems	None
6	ANSI/AAMI/ISO 11137-1:2006/(R) 2010	Sterilization of health care products – Radiation –Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	None
7	ANSI/AAMI/ISO 11137-2:2012	Sterilization of health care products – Radiation –Part 2: Establishing the sterilization dose	None

Guidance Document: The recommendations of the FDA's "Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Cutaneous Electrode (April 5, 2010)" were taken into account in preparing this 510(k) submission.

Performance Data:

Design validation of the ISSDE was confirmed and documented. Tests to measure impedance and variation of energy distribution, which determine safety and efficacy, were conducted to compare the ISSDE to three predicate devices.

Values of current were calculated from testing each electrode. Impedance values were tabulated for all gel electrodes using samples per electrode type. Impedance values for the ISSDE are confirmed to be substantially equivalent to predicate devices

Variation of energy distribution was also determined to be substantially equivalent, which confirms avoidance of hot spots.

The results of the impedance and variation of energy distribution tests conducted confirm that the ISSDE design is substantially equivalent to three FDA cleared predicate devices.

Performance data for the Proposed ISSDE is compared to that of the predicate devices mentioned above. Results from the biocompatibility study, physical and functional performance evaluation demonstrate that the Proposed ISSDE is substantially equivalent to the legally marketed devices.

Substantial Equivalence Table:

Substantial Equivalence Item	**InterX Sterile Self-Adhesive Dual Electrode (ISSDE) (New Device)**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**
Sterile	YES	NO	YES	NO
Intended Use	Sterile, post-operative, reusable, self-adhesive, stimulating electrode (single patient)	Non-sterile, reusable, self-adhesive, stimulating electrode (single patient)	Sterile, post-operative, self-adhesive, stimulating electrode (single patient)	Non-sterile, reusable, self-adhesive, stimulating and recording electrode (single patient)
Indications for Use	ISSDE is indicated for use with InterX Transcutaneous Electrical Nerve Stimulator. The ISSDE provides the conductive interface between the InterX stimulation device and the patient's skin. The ISSDE is not made with natural rubber latex, is reusable (single patient only), and is provided packaged and labeled as a sterile device, for single patient use.	The Superior Starburst Reusable Self-adhering TENS/NMES/FES Stimulating Electrodes are indicated for use with transcutaneous electrical stimulation devices as non-sterile, Latex free, reusable device for single patient use only. The electrodes provide the conductive interface between the stimulation device and the patient's skin.	The Sterile Post Op Self-adhering TENS Stimulating Electrodes are indicated for use with transcutaneous electrical stimulation devices as sterile, Latex free for single patient use only. The electrodes provide the conductive interface between the stimulation device and the patient's skin.	The Classic Reusable Self-adhering TENS/NMES/FES Stimulating Electrodes are indicated for use with transcutaneous electrical stimulation devices as non-sterile, Latex free, reusable device for single patient use only. The electrodes provide the conductive interface between the stimulation device and the patient's skin.
Hydrogel Volume Resistivity	1500 ohm-cm (max)	2500 ohm-cm (max)	2500 ohm-cm (max)	2500 ohm-cm (max)
Electrode Area (surface area in contact with skin)	67.58 cm^2	50.23 cm^2	57.64 cm^2	47.47 cm^2

Substantial Equivalence Item	**InterX Sterile Self-Adhesive Dual Electrode (ISSDE) (New Device)**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**
Hydrogel Biocompatibility ISO 10993-1	Cytotoxicity Test – Passed Delayed Contact Hypersensitivity Test – Passed Primary Skin Irritation Test – Passed	Cytotoxicity Test – Passed Delayed Contact Hypersensitivity Test – Passed Primary Skin Irritation Test – Passed	Cytotoxicity Test – Passed Delayed Contact Hypersensitivity Test – Passed Primary Skin Irritation Test – Passed	Cytotoxicity Test – Passed Delayed Contact Hypersensitivity Test – Passed Primary Skin Irritation Test – Passed
Hydrogel Stainless Steel Adhesion (180° peel)	136 grams minimum	136 grams minimum	180 grams minimum	136 grams minimum
Conductive Electrode Element	Carbon film with silver flood coated over entire surface	Carbon film with silver flood coated gradient pattern	Carbon film with silver flood coated over entire surface	Carbon film with silver flood coated over entire surface
Electrode Top Cover	Non-Conductive White Polyethylene Foam, 31.25 mils thick	Non-Conductive White Tricot	Non-Conductive White Polyethylene Foam, 31.25 mils thick	Non-Conductive White Polyethylene Foam, 31.25 mils thick
Sterilization Method	Gamma Sterilized	N/A	Gamma Sterilized	N/A
Storage Liner	Polyester with silicone release	Polyester with silicone release	Silicone coated bulk paper	Polyester with silicone release
Electrode Lead Wire	2-conductor cable, 24 AWG tinned copper conductors with PVC jacket	Single conductor 24 AWG tinned copper with PVC jacket	Single conductor 24 AWG tinned copper with PVC jacket	Single conductor 24 AWG tinned copper with PVC jacket
Electrode Packaging	Sealed Pouch	Sealed Pouch	Sealed Pouch	Sealed Pouch
Number per Package	1	4	2	4
Electrode Permanence	Disposable	Disposable	Disposable	Disposable
Patient Preparation	Clean Dry Skin	Clean Dry Skin	Clean Dry Skin	Clean Dry Skin
Electrode Placement	On Patient Skin In Intended Treatment Area	On Patient Skin In Intended Treatment Area	On Patient Skin In Intended Treatment Area	On Patient Skin In Intended Treatment Area
Latex Content	Not made with natural rubber latex	Latex Free	Latex Free	Latex Free

Substantial Equivalence Item	**InterX Sterile Self-Adhesive Dual Electrode (ISSDE) (New Device)**	**Predicate Device 1**	**Predicate Device 2**	**Predicate Device 3**
Electrode Impedance @ 1000 Hz	Less than 50 ohms	Less than 50 ohms	Less than 50 ohms	Less than 50 ohms
Wire Attachment Integrity (force to remove lead wire from electrode)	More than 25 lbs. force	More than 10 lbs. force	More than 10 lbs. force	More than 15 lbs. force
Connector Disengagement Force	More than 2 lbs. force	More than 2 lbs. force	More than 1.75 lbs. force	More than 2 lbs. force
Connector Design	Overmolded keyed connector with 2-pole 1.0 mm sockets, touch-proof	Overmolded .080" single pole socket, touch-proof	.080" single pole socket with heat shrink covering, touch-proof	Overmolded .080" single pole socket, touch-proof
21 CFR 898 Compatible?	Yes	Yes	Yes	Yes
Lead Wire to Electrode Attachment Method	Cyanoacrylate adhesive between wire insulation and silver film, tinned copper wire in contact with silver film	Cyanoacrylate adhesive between wire insulation and silver film, tinned copper wire in contact with silver film	Cyanoacrylate adhesive between wire insulation and silver film, tinned copper wire in contact with silver film	Cyanoacrylate adhesive between wire insulation and silver film, tinned copper wire in contact with silver film

Conclusions:
The Proposed ISSDE is similar in intended use, functional design, principles of operation, materials, packaging and other technological characteristics to the predicate devices. After analyzing the performance and testing, it is concluded that the ISSDE is as safe and effective as the predicate devices and do not raise any new issues of safety and effectiveness.

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 21, 2013

Neuro Resource Group, Inc.
c/o David Turner, CEO
Neuro Resource Group
1100 Jupiter Road, Ste. 190
Plano, TX 75074

Re: K130816
Trade/Device Name: InterX Sterile Self-Adhesive Dual Electrode (ISSDE)
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: March 13, 2013
Received: March 25, 2013

Dear Mr. Turner:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):____K130816

Device Name:___ InterX Sterile Self-Adhesive Dual Electrode (ISSDE)

Indications For Use:

ISSDE is indicated for use with InterX Transcutaneous Electrical Nerve Stimulator. The ISSDE provides the conductive interface between the InterX stimulation device and the patient's skin. The ISSDE is not made with natural rubber latex, is reusable (single patient only), and is provided packaged and labeled as a sterile device, for single patient use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number _K130816_____