June 14, 2019

Shenzhen Bestpad Technology Development Co., Ltd
% Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg. 1
Southward Ruifeng Business Center, Guimiao Road
Shenzhen, Guangdong, 518000 Cn

Re: K190700
Trade/Device Name: Electrodes Pad
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 25, 2019
Received: March 18, 2019

Dear Rain Yip:

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,

Vivek Pinto, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190700

Device Name
ELECTRODES PAD

Indications for Use *(Describe)*
ELECTRODES PAD is intended to transmit electrical current to patient skin for use with legally marketed electrical stimulation devices, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The PAD is for OTC (Over-The-Counter) or Prescription use. The PAD is for adults only.

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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510(k) Summary

"510(k) Summary" as required by 21 CFR Part 807.92.

Date: 2019-02-25

I. Submitter

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II. Device

Type of 510(k): Traditional
Trade Name: ELECTRODES PAD
Models: leadwire type electrode and snap type electrode
Common Name: Cutaneous Electrode
Classification Name of the device: Cutaneous Electrode
Review Panel: Neurology
Regulatory Class: II
Product Code: GXY
Regulation Number: 21 CFR 882.1320

III. Predicate Device

Applicant	Predicate Device	510(k) Number	Approval Date
ShenZhen Quality Medical Technology Co., Ltd	Adhesive Electrodes	K171381	Dec.13, 2017
Wandy Rubber Industrial Co., Ltd	Wandy Self-adhesive Electrode	K132998	Dec.20, 2013

IV. Device Description

ELECTRODES PAD transmit electrical current to patient skin, the electrical current is first transmitted via the snap button or lead wire then transmitted to the conductive hydrogel which is adhered to patient skin.

ELECTRODES PAD is intended to transmit electrical current to patient skin for use with legally marketed electrical stimulation devices, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The PAD is for OTC (Over-The-Counter) or Prescription use. The PAD is for adults only. And the PAD is designed for single-patient and multiple application use.

1) Device specifications

Model	Electrical connection method	Insulation backing material(s)	Product size (mm)	Connector size (Hole diameter) (mm)
Leadwire type electrode	**Leadwire**	Non-woven /PU /PVC /PET /EVA foam /silicone	Length: 20~300 Width: 20~300 Height (thickness): 1~20	**1.5, 2.0, 2.5, 3.0**
Snap type electrode	**Snap button**	Non-woven /PU /PVC /PET /EVA foam /silicone	Length: 20~300 Width: 20~300 Height (thickness): 1~20	**3.2, 3.6, 3.8, 4.0, 4.2**

2) Device design

The leadwire type electrode and snap type electrode both have six basic components. See Figure 1 and Figure 2 for the structure picture of the both model.

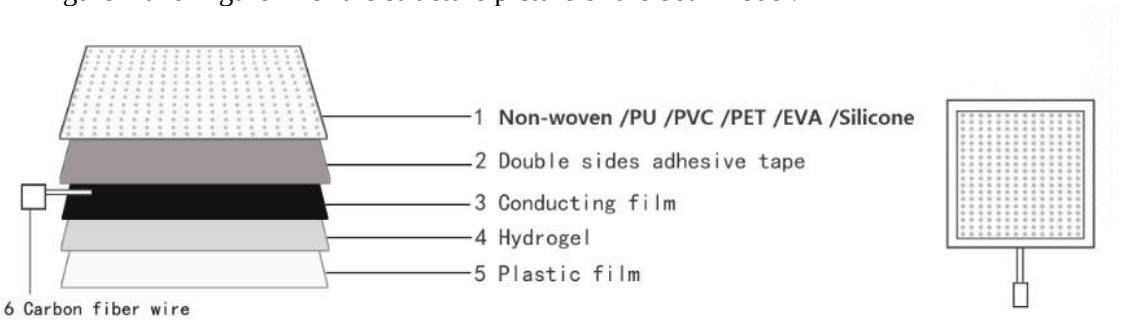

Figure 1 The structure of leadwire type electrode

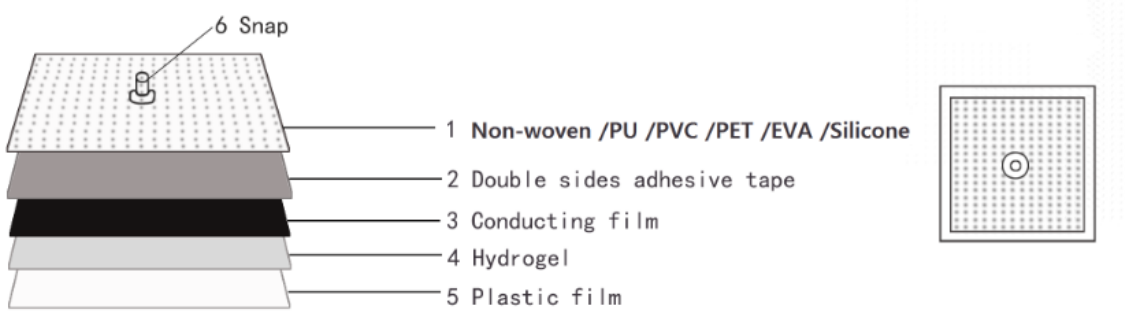

Figure 2 The structure of snap type electrode

3) Materials used

Both models are composed of an insulation backing layer, a double sides adhesive tape, conducting film, hydrogel and plastic film. The construction different between both is leadwire and snap.

Material of construction:

Component	Description /Material of Construction
Insulation backing layer	☐Non-woven/☐PU/☐PVC/☐PET/☐EVA

Component	Description /Material of Construction
	foam/☐silicone
Double sides adhesive tape	This layer is used to connect the upper and lower layers.
Conducting film	Conductive carbon film
Gel	Conductive hydrogel
Protective film layer	Plastic film
Electrical connection layer	☐Leadwire: carbon fiber wire ☐Snap: stainless steel

4) Physical and performance characteristics of the device
   Electrical impendence: <300 ohms
   Adhesive performance: 30 minutes maximum duration use, in total 30times
5) Principle of operation
   ELECTRODES PAD functions as a passive device by carrying an electrical signal from a stimulation device through the device cable and electrode lead wire or snap to the user skin. Electrical signal from a stimulation device is connected to the electrode pad through a lead wire or snap, which is dispersed across the conductive film, then transmitted through the conductive adhesive hydrogel to the surface of the patient's skin.

V. Indications for Use / Intended Use

ELECTRODES PAD is intended to transmit electrical current to patient skin for use with legally marketed electrical stimulation devices, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The PAD is for OTC (Over-The-Counter) or Prescription use. The PAD is for adults only.

VI. Comparison of Technological Characteristics With the Predicate Device

The subject device ELECTRODRS PAD has the same intended use and principle operation, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicated devices. The differences between the subject device and predicate devices do not alter suitability of the subject device for its intended use.
Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicate is provided below:

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Discussion**
K Number	K190700	K171381	K132998	N/A
Device name/model	ELECTRODES PAD/ Leadwire type electrode and Snap type electrode	Adhesive Electrodes	Wandy Self-adhesive Electrode	N/A
Regulation number	21CFR 882.1320	21CFR 882.1320	21CFR 882.1320	Same
Product code	GXY	GXY	GXY	Same
Classification name	Cutaneous electrode	Cutaneous electrode	Cutaneous electrode	Same
Location for use	OTC and	OTC and	OTC and	Same

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**	**Discussion**
	Prescription	Prescription	Prescription	
Intended use/Indications for Use	ELECTRODES PAD is intended to transmit electrical current to patient skin for use with legally marketed electrical stimulation devices, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). . The PAD is for OTC (Over-The-Counter) or Prescription use. The PAD is for adults only.	The Adhesive Electrodes are intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications. It is for OTC (Over-The - Counter) or Prescription use and is to be used for adults only.	Wandy Self-adhesive Electrode is intended to transmit electrical current to patient skin for TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation) applications, for OTC (Over-The - Counter) or Prescription use.	SE NOTE 1
Design feature	Six basic components for the electrode: -Electrical connecting layer: Carbon fiber wire/Snap button -Insulation backing material: non-woven/PU/PVC/PET/EVA foam/Silicone -Double sides adhesive tape -Conducting film: carbon film -Hydrogel -Protective film layer: Plastic film	Three layers: 1. Insulation backing material: EVA foam 2. Conductive film: Carbon film 3. Conductive hydrogel Protective line: PET	Three layers: 1. Insulation backing material: Woven Fabric/Foam 2. Conductive film: Aluminum/Carbon 3. Conductive hydrogel Protective line: PET	SE NOTE 2
Electrical connection	Leadwire Snap button	Snap button	Snap button or lead wire	SE
Electrical	<300 ohms	< 300 ohms	< 300 ohms	Same

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2	Discussion
impendence				
Sterility status	Non-sterile	Non-sterile	Non-sterile	Same
Reusable or Disposable?	Reusable	Reusable	Reusable	Same
Shelf life (Storage life)	2 years	Unknown	Unknown	NOTE 3
Single patient use?	Yes	Yes	Yes	Same
Target population	Adult	Adult	Adult	SE
Patient contacting material	Hydrogel	Hydrogel	Hydrogel	SE NOTE 5
Self-adhesive	Self-adhesive	Self-adhesive	Self-adhesive	Same
Biocompatibility feature	Complied with ISO10993	Complied with ISO10993	Complied with ISO10993	SE NOTE 5

Comparison in details:

NOTE 1: Although the descriptive text of the "Intended use/Indication for Use" of the subject device is minor different from the predicate device, they are having the substantially equivalent intended purpose. So the differences of descriptive text will not affect its intended use.

NOTE 2: The subject device is designed as multi-layer reusable, flexible structures, composed of laminated materials commonly used in this application. Although the descriptive text of the "Design feature" of the subject device is different from the predicate device, they are having basically substantially equivalent design feature and the subject device has more detailed description:
--The electrical connecting layer of the subject device is by the mean of snap button or lead wire, in the range of the predicate devices.
--The subject device has various insulating backing materials, but it does not impact safety and effectiveness of the subject device;
--The component of double sides adhesive tape is used to connect the upper and lower layers, it won't raise any concerns of safety or effectiveness.
--The subject device contains carbon film as a conductive film, in the range of the predicate devices;
--The conductive layer of the subject device and predicate devices all are conductive hydrogel, and passed the biocompatibility tests;
--The subject device adopts plastic film as a protective film layer, substantially equivalent to the predicate devices.

NOTE 3: The shelf life of the subject device has conducted the shelf life verification according to FDA Guidance –Shelf Life of Medical Device and ASTM F1980-07 Standard. And the verification has passed.

NOTE 5: The patient contacting material of the subject device and predicate devices all are hydrogel, although their supplier is not sure, they are all complying with ISO 10993 requirements. So this part will not raise any safety or effectiveness issue.

VII. Performance Data

1) Brief discussion of clinical tests

Not applicable.

2) Brief discussion of the nonclinical tests:

Biocompatibility Testing: The ELECTRODES PAD has tested and passed the biocompatibility tests: cytotoxicity, skin irritation, and skin sensitization. And the tests are performed according to the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on June 16, 2016", as recognized by FDA.

Performance Testing:

- The lead wire part is compliance with 21 CFR 898 by IEC 60601-1:2005/A1:2012 Medical Electrical Equipment –Part 1: General Requirements for Basic Safety and Essential Performance –Subclause 8.5.2.3.
- The Delivery Test Report has been conducted to verify the product properties before factory delivery according to the manufacturer's acceptance criteria.
- The Adhesion Test Report has been conducted to verify the maximum use duration of the subject device according to the requirements of the AAMI EC 12_2000(R) 2010 –Section 5.4.
- The Dispersion and Shelf Life Test Report has been conducted to verify the current dispersion and shelf-life of the subject device in the expiration date according to the requirements of the FDA Guidance –Shelf Life of Medical Device and ASTM F1980-07 Standard.

Summary

Based on the above performance as documented in this application, ELECTRODES PAD was found to have a safety and effectiveness profile that is similar to the predicate devices.

VIII. Conclusions

The subject device ELECTRODES PAD is to be concluded substantial equivalent to its predicate devices.