DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 19, 2016

Cathay Manufacturing Corp.
% Mr. Fan, Tao
Consultant
Shanghai YunTao Management Consultant
Room 202, No. 14, Lane 986, Gaosi Road
Pudong District
Shanghai, 201203 China

Re: K160081
Trade/Device Name: TENS Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: September 3, 2016
Received: September 19, 2016

Dear Mr. Fan, Tao:

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 and Part 809); 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 801and Part 809), 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" (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 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,

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

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)*
K160081

Device Name
TENS Electrodes

Indications for Use *(Describe)*
The proposed device is intended for use as the disposable, conductive adhesive interface between the patient's skin and the electrical stimulator to apply electrical stimulation current, and is intended to be used with marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).
It's for OTC 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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510(k) Summary

Submitter: CATHAY MANUFACTURING CORP.
No. 328, Xishe Road, Maogang Town, Songjiang Area
Shanghai, CN 201607

Contact: Mr. Fan, Tao
Phone: (86)18616806984
Fax: (86)-21-57876338
fant01@uwellmed.com

Date Prepared: Oct. 18, 2016

Device Trade Name: **TENS Electrodes**

Device Common Name: **Neurostimulation Electrodes**
Classification name: **Cutaneous Electrodes**

Class: **II**

Regulation: 882.1320

Product Code: **GXY**

Primary Predicate Device:

Device	Company	Product Code	510(k) Number
SELF-ADHESIVE ELECTRODES	CATHAY Healthcare Equipment Manufacturing Inc.	GXY	K080276

A Reference Device Chosen:

Top-Rank Adhesive Electrodes	Top-Rank Health Care Co., Ltd	GXY	K132588

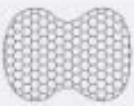
1. Indication for Use:

The proposed device is intended for use as the disposable, conductive adhesive interface between the patient's skin and the electrical stimulator to apply electrical stimulation current, and is intended to be used with marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).
It's for OTC use.

2. Product Description:

The proposed TENS Electrodes are non-sterile laminated, flexible structures composed of materials commonly used in this application:
The electrodes are designed for single-patient application use. Because of the adhesive nature of the biocompatible hydrogel, no securing materials are required to secure the device to the patient's skin.

The proposed device mainly consists of electrode pad and wire. The electrode pad is available in rectangular shape, round shape, and butterfly shape, etc.

Shape	Product Model		Shape	Product Model	
	☐ CM2040FC	☐ CM5570FC		☐ CM2222FC	☐ CM6060FC
	☐ CM3050FC	☐ CM5575FC		☐ CM3232FC	☐ CM6565FC
	☐ CM3060FC	☐ CM5590FC		☐ CM4040FC	☐ CM7070FC
	☐ CM4050FC	☐ CM6070FC		☐ CM4545FC	☐ CM7575FC
	☐ CM4060FC	☐ CM6080FC		☐ CM4848FC	☐ CM8080FC
	☐ CM4070FC	☐ CM6090FC		☐ CM5050FC	☐ CM8585FC
	☐ CM4080FC	☐ CM60100FC		☐ CM5555FC	☐ CM9090RC
	☐ CM4090FC	☐ CM7080FC		☐ CM22RC	☐ CM60RC
	☐ CM40100FC	☐ CM70100FC		☐ CM25RC	☐ CM65RC
	☐ CM4580FC	☐ CM70120FC		☐ CM32RC	☐ CM70RC
	☐ CM4590FC	☐ CM75125FC		☐ CM40RC	☐ CM75RC
	☐ CM45100FC	☐ CM80100FC		☐ CM45RC	☐ CM85RC
	☐ CM5060FC	☐ CM80110FC		☐ CM50RC	☐ CM90RC
	☐ CM5070FC	☐ CM80120FC		☐ CM55RC	
	☐ CM5090FC	☐ CM80130FC		☐ CM4050TC	☐ CM5580SC
	☐ CM50100FC	☐ CM90120FC		☐ CM4560TC	☐ CM7090TC
	☐ CM50130FC	☐ CM90130FC		☐ CM4570SC	
	☐ CM5565FC	☐ CM100180FC		☐ CM2542YC	

wire: ☐ϕ 2.0mm ☐ϕ 2.5mm
Packaging : ☐2PCS ☐4PCS ☐6PCS ☐8PCS ☐12PCS ☐24PCS

4. Summary of Technology Characteristics and Performance Testing (Comparison to the Primary Predicate Device and Reference Device)

ELEMENT OF COMPARISON	SUBJECT DEVICE	Primary Predicate Device K080276 SELF-ADHESIVE ELECTRODES	A Reference Device chosen K132588 Top-Rank Adhesive Electrodes
Indications for Use	The proposed device is intended for use as the disposable, conductive adhesive interface between the patient's skin and the electrical stimulator to apply electrical stimulation current, and is intended to be used with marketed electrical stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It's for OTC use.	The electrotherapy electrodes are intended to be used to apply electrical stimulation current to the patient's skin or record physiological signals	Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS(Electrical Muscular Stimulation). It's for OTC use.
OTC or Prescription	For OTC Use	For Prescription use	For OTC use
Sterility	Non-sterile	Non-sterile	Non-sterile
Design Features	Substrate / Wire/ Hydro-Gel Scrim / Conductive Fiber Carbon Conductive Film /	Substrate / Wire/ Hydro-Gel Scrim / Conductive Fiber Carbon Conductive Film / Liner	Substrate / Wire/ Hydro-Gel Scrim / Conductive Fiber Carbon Conductive Film / Liner
Materials: Substrate; Wire; Hydro-gel; Scrim; Conductive fiber; Carbon conductive film; Liner	Non-woven fabric+ adhesive	Non-woven fabric+ adhesive	Non-woven fabric+ adhesive
	Wire & Terminal coated PVC	Wire & Terminal coated PVC	Wire & Terminal coated PVC
	Hydro-gel	Hydro-gel	Hydro-gel
	PET fabric	PET fabric	PET fabric
	Carbon fiber + reinforcing fiber	Carbon fiber + reinforcing fiber	Carbon fiber + reinforcing fiber
	Poly-isobutylene, Carbon Black	Poly-isobutylene, Carbon Black	Poly-isobutylene, Carbon Black
	Transparent PET liner coated silicon	Transparent PET liner coated silicon	Transparent PET liner coated silicon
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993	Conforms to ISO10993
Labeling	confirm to 21 CFR Part 801	confirm to 21 CFR Part 801	confirm to 21 CFR Part 801
Performance	Conforms to IEC 60601-1 and IEC 60601-2-10:2012, Part 2 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	Conforms to IEC 60601-1 and IEC 60601-2-10:2012, Part 2 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	Conforms to IEC 60601-1 and IEC 60601-2-10:2012, Part 2 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.
Electrical impedance	Individual pad impedance below 200 ohms @ 60 kHz	By linking the connector to gel using a multi-meter. Set the range at x1k ohm. Pass if the needle of multi-meter moves	By linking the connector to gel using a multi-meter. Set the range at x1k ohm. Pass if the needle of multi-meter moves

ELEMENT OF COMPARISON	SUBJECT DEVICE	Primary Predicate Device K080276 SELF-ADHESIVE ELECTRODES	A Reference Device chosen K132588 Top-Rank Adhesive Electrodes
Electrode types, shapes, and sizes used for testing	Largest model: CM100180FC (Rectangle shape: 100 x 180 mm); Smallest model: CM2222FC(square shape: 22 x 22 mm); Irregular representative: CM2542YC(crescent)	Largest and irregular model: CM100200 (butterfly shape: 100 x 200 mm) Smallest model: CM2222 (Square shape: 22 x 22 mm)	A most common used sample: AF5050WP(Square Shape: 50 x50 mm)
Adhesive performance on T_0	>= No.14 steel ball (Diameter: 11.112 mm) following AS07-003 / GB/T4852-2002	>= No.14 steel ball (Diameter: 11.112 mm) following AS07-003 / GB/T4852-2002	>= No.14 steel ball (Diameter: 11.112 mm) following AS07-003 / GB/T4852-2002
Adhesive holding strength performance	A sample pad with 25mm length and 25 mm width; Hang a weight of 200g without detach within 30s	A sample pad with 25mm length and 25 mm width; Hang a weight of 200g without detach within 30s	A sample pad with 25mm length and 25 mm width; Hang a weight of 200g without detach within 30s
Tensile Strength	Electrode is held up with a weight of 500g hung on the wire, and can hold on at least 1 minutes	Electrode is held up with a weight of 500g hung on the wire, and can hold on at least 1 minutes	Electrode is held up with a weight of 500g hung on the wire, and can hold on at least 1 minutes
Conformability Test	No more than 10% of the adhesive area of the device shall have separated from the skin surface at 1 h after application.	No more than 10% of the adhesive area of the device shall have separated from the skin surface at 1 h after application.	No more than 10% of the adhesive area of the device shall have separated from the skin surface at 1 h after application.
Impedance Distribution uniformity test	1) No significant deviation between resistance values measured for each combination mode. 2) The maximum value and the minimum value should be within ±10% of average value	1) No significant deviation between resistance values measured for each combination mode. 2) The maximum value and the minimum value should be within ±10% of average value	1) No significant deviation between resistance values measured for each combination mode. 2) The maximum value and the minimum value should be within ±10% of average value
Stability and shelf life	2 year	2 year	2 year
Re-usable	For single patient	For single patient	For single patient
Intended population	No specified population	No specified population	No specified population

Comparison Summary	Compare to primary predicate device specified in K080276, our device and the predicate device are same in Essential Components, raw materials, physical features, and same manufacturing processes. One difference is that our proposed device does not claim for recording physiological signals as the predicate device does. Another difference is predicate device is intended for prescription use, and our proposed product is for Over-the-Counter (OTC) use. Our product and the predicate device are the same in intended for use, essential components, physical and general safety features based on ISO international standards. The hydro-gel used in K080276 is not different from what is used in CATHAY TENS Electrodes. Compare to both primary predicate device and reference device, the proposed device has different test method for electrical impedance. However, this test method is a more sensitive & improved test method. Previously, proposed device test method for electrical impedance was exactly the same as predicate device and reference device, and all tests can pass previous test method also. Compare to the primary predicate device and reference device, the subject device is constructed in the same manner, is constructed of same or similar materials, have same or similar indications for use, and have similar performance characteristics Any minor visual, dimensional or labeling differences between the primary predicate device and reference device and the proposed electrodes do not pose risk to their performance and usage.

5. Bench Testing (non-clinical):

Compare to primary predicate product specified in K080276, our device and the predicate device are same in Essential Components, raw materials, physical features, and same manufacturing processes. The biocompatibility performance equivalence evidence of proposed electrode can be demonstrated.

The proposed TENS Electrodes evaluated through Electrode Performance testing (Electrical Impedance Performance, Adhesive Performance, and Tensile Strenght), Biocompatibility testing, Stability testing, and Reuse testing.

The comparison tests conclusively prove that the proposed electrode is similar / equivalence as performance efficient at electrical impedance, adhesive performances, tensile strength, conformability, and impedance distribution uniformity performance as the primary predicate device and reference device.

For lead wires & cables used in proposed device, the safety performances are demonstrated by the Third party, TUV Rheiland, through testing following IEC

60601-1:2005+CORR. 1(2006) + CORR.2(2007) + AM1(2012), Part 1General requirements for basic safety and essential performance, and IEC 60601-2-10:2012, Part 2 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.

The results of bench testing & type testing provide reasonable assurance that the proposed device has been designed and validated to assure conformance to the requirements for its indication for use.

6. Conclusion:

Based on the indication for use, technology characteristics, and performance testing, the proposed product, TENS Electrodes, has been shown to be appropriate for its indication for use and is considered to be substantially equivalent to the primary predicate device and reference device.