November 4, 2022

Guangdong Comytens Medical Technology Co., Ltd
Mr. Amos Zou
RA Manager
Building A-102, No. 24, Jiangjunmao Industrial Zone
Wulian, Longgang District
Shenzhen, Guangdong 518116
China

Re: K222453
Trade/Device Name: Self-adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 12, 2022
Received: August 15, 2022

Dear Mr. Amos Zou:

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,

Tushar Bansal -S

Tushar Bansal, PhD
Acting 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)*
K222453

Device Name
Self-adhesive Electrode

Indications for Use *(Describe)*
Self-Adhesive Electrode is intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e.TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC(Interferential current),or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, 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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510(K) SUMMARY

1. Submitter of 510(K):

Sponsor

Company Name:	Guangdong Comytens Medical Technology Co.,Ltd
Address:	Building A-102, No. 24, Jiangjunmao Industrial Zone, Wulian, Longgang District , Shenzhen, Guangdong, China 518116
Contact person:	Deng Jiuzhen
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E-mail:	info@comytens.com 276148005@qq.com
Date of Prepared:	Nov, 3 2022

Application Correspondent:

Company Name:	Guangdong Comytens Medical Technology Co.,Ltd
Address:	Building A-102, No. 24, Jiangjunmao Industrial Zone, Wulian, Longgang District , Shenzhen, Guangdong, China 518116
Contact person:	Amos Zou
TEL:	+86-15015249549
E-mail:	Amos.zou@139.copm
Date of Prepared:	Nov, 3 2022

2. Proposed Device and code:

Device Trade Name:	Self-Adhesive Electrode
Model Series	Self-Adhesive Electrodes with lead wire; Self-Adhesive Electrodes with Snap/Magnetic connector; Self-Adhesive Electrode Pads
Regulation Medical Specialty	Neurology

Product Code:	GXY
Regulation number	21 CFR 882.1320
Device Class	II
510(K) Number	K222453

3. Predicate Device:

510(K)	Trade Name	Submitter	Product Code
K180865	ZMI Self-adhesive	ZMI Electronics, Ltd.	GXY

4. Description of Proposed Device:

Self-Adhesive Electrodes are composed of conductive carbon film and adhesive Electrodes composed of Aluminum foil film,Adhesive Electrodes manufactured by Comytens are multi-layer reusable, flexible structures composed of laminated materials commonly used in this application:

No.	Description	Material Composition
1	Top layer	Fabric/Foam/ Tan fabric
2	Middle layer	Conductive film (Silver coated Carbon Film/Carbon film/Aluminum foil film)
3	Bottom layer	Biocompatible self-adhesive conductive hydrogel
4	Connection	Leadwire/snap button/magnetic button
5	double sides adhesive tape	which is used for attaching the non-woven fabrics and conducting film
6	Release liner	plastic film is a protective layer for the hydrogel.

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

For the electrical connection, Comytens provides lead wire type and snap button/Magnetic button type:

- Leadwire assembly:

The electrode is connected to the electrical stimulator by lead wire, at least 40 mm long wire with a standard connector: 0.08″/0.1″(2mm/2.5mm) diameter female socket connector with insulating outer. By design, the insulated outer jacket prevents the conductive connection to earth or hazardous voltages. The lead wire assembly is in compliance with the requirements of FDA performance standard 21 CFR part 898 by testing under ANSI/AAMI ES60601-1, subclause 8.5.2.3.

- Snap button/Magnetic button assembly:

With 2.5~5mm diameter male socket. The snap button and the magnetic button provide different types of physical contact with the source of stimulation current via spring tension or magnetic force among male and femaleconnectors. Either method is similar to the lead wire connection providing the friction to create the physicalcontact.

5. Intended for Use

Self-Adhesive Electrode is intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e.TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC(Interferential current), or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

Comparison to predicate device:

Element of Comparison	Subject Device	Predicate Device	Comment
510(k)	K222453	K180865	N/A
Company	Guangdong Comytens Medical Technology Co.,Ltd	ZMI Electronics, Ltd.	N/A
Device Name	Self-Adhesive Electrodes	ZMI Self-adhesive electrodes	N/A
Model name	● Self-Adhesive Electrodes with leadwire; ● Self-Adhesive Electrodes with Snap /Magnetic connector; ● Self-Adhesive Electrode Pads	SAE Type	N/A
Shape	Square(40*40mm)	Round, Rectangular, Square, Oval, and Butterfly	similar 1#
Color	White, Red, Black, and Tan	White, Red, Black, and Tan	Same
Regulation Number	882.1320	882.1320	Same
Product Code	GXY	GXY	Same
Classification Name	Cutaneous electrode	Cutaneous electrode	Same
Intended Use	Self-Adhesive Electrode is intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e.TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF or IFC(Interferential current) , RUSS(Russian stimulation), MIC(Microcurrent) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.	ZMI Self-adhesive electrodes are intended for as a reusable, conductive adhesive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current, for OTC (Over-The-Counter) or Prescription use.	Same
OTC or Prescription	OTC and Prescription	OTC and Prescription	Same
Target Population	General [Adult]	General [Adult]	Same
Design Feature	Six layers: 1. Insulation backing material: Fabric/Foam/ Tan fabric 2. Conductive film: Aluminum foil film	Three layers: 1. Insulation backing material: Fabric/Foam/ Tan fabric 2.Conductive film: Aluminum foil	similar 2#

	/Carbon film/Carbon film coated with silver/ 3.Conductive hydrogel 4.Connection 5.double sides adhesive tape 6.Release liner	film/Carbon film/Carbon film coated with silver/ 3.Conductive hydrogel	
Electrical Connection	Leadwire Snap button Magnetic button	Leadwire Snap button Magnetic button	Same
Lead Wire connector	.080”/0.1”(2mm/2.5mm) female socket or Pin connector	.080” (2mm) female socket connector	similar 3#
Non-sterile	Non-sterile	Non-sterile	Same
Reusable	Reusable	Reusable	Same
Packaging	Re-sealable bag packed	Re-sealable bag packed	Same
Adhesive Type	Self-adhesive	Self-adhesive	Same
Biocompatibility	Complies with ISO10993	Complies with ISO10993	Same
A.C. Impedance	<200 ohms	<200 ohms	Same
Force required to remove wire from electrode	More than 6 pounds of force	More than 6 pounds of force	Same
Single Patient Use	Yes	Yes	Same

Comparison in Detail(s):

1#: The shape and size are related to the treatment area. Smaller area may cause higher current density, which leads to discomfort and burns. The current densities for any shaped electrodes exceeding 2mA r.m.s/cm2 may require the special attention of the user. The color is mainly for identification and marketing purpose, and does not raise any new concerns of safety or effectiveness.

If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility.

2#: The subject device and predicate device are similar in construction. They both contain three basic components: a non-conductive top layer, a patient contacting layer, a carbondispersion pad middle layer, and; while the Self-Adhesive Electrode also contains three additional layer:conductive carbon fiber lead wire (or snap for Magnetic Style Electrode),double sides adhesive tape which is used for attaching the non-woven fabrics and conducting film,and plastic film is a protective layer for the hydrogel. Which the differences will not affect the safety and effectiveness of the Self-Adhesive Electrode.

3#: The snap button and the magnetic button provide different types of physical contact with the source of stimulation current via spring tension or magnetic force among male and female connectors. Either method is similar to the lead wire connection providing the friction to create the physical contact.

7. Performance Testing:
Test Summary:
To establish substantial equivalence to the identified predicate devices, we performed the following tests on the subject device, Adhesive Electrodes TS serial,and the testing results provide evidence that the device complies with the applicable standards requirement and it is substantially equivalent to the predicate devices.
Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

7.1 Non-Clinical Data:
Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrate that the proposed device complies with the following standards:

7.2 Biocompatibility testing
The biocompatibility evaluation for the Self-Adhesive Electrode 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 worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

7.3 Safety and EMC
To verify the basic safety and essential performance of the subject device, weperformed the test noted below:
- IEC60601-1:2005+AMD1:2012+AMD2:2020， Medical electrical equipment – Part 1: General requirementsfor basic safety and essential performance
The submitted sample(s) complied with the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020, Cl.8.5.2.3

7.4 Bench Testing
Bench tests were conducted on Self-Adhesive Electrode to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
1. Electrical & Impedance Tests
The Self-Adhesive Electrode was tested to assure the current is equally distributed.The Self-Adhesive Electrode was also tested for Impedance to assure proper electrical connection to the skin.
2. Adhesion tests
The Self-Adhesive Electrode was tested for initial adhesion force and adhesion force after using multiple times.
3. Connector & Mechanical tests
The Self-Adhesive Electrode has a Snap or magnetic surface with the purpose to clamp the Self-Adhesive Electrode. This connection was tested to assure multiple use and also to assure the TENS stay fixed to the Self-Adhesive Electrode during use.
4. Packaging testsReal-Time Shelf Life Test Report
The Self-Adhesive Electrode was tested for storage conditions:
• The Self-Adhesive Electrode should not be stored at temperatures lower than 41°F(+5°C) or higher than 80.6°F (+27°C).
5. Accelerated Aging
The Self-Adhesive Electrode was tested for accelerate aging in worst storage condition to assure within the expiration date the electrode function as expected.
- ASTM F1980 (Reapproved 2016), Standard guide for accelerated aging of sterile barrier systems for medical devices. (Sterility)

7.5 Clinical data:
No clinical testing was performed

7.6 Summary
Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions:
The proposed device has the same intended use and similar characteristics as the predicate device, Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Guangdong Comytens Medical Technology Co.,Ltd. maintains that the Self-Adhesive Electrode is substantially equivalent to the

predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.