



August 31, 2021

Shaoxing Yingtuo Healthcare Co., Ltd.
Haze XU
Management Representative, Quality Department
NO.176 Shungeng Road, Baiguan Street, Shangyu Area
Shaoxing City, Zhejiang Province 312300
China

Re: K210448
Trade/Device Name: adhesive electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: July 29, 2021
Received: August 5, 2021

Dear Haze XU:

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,


Heather L. Dean -S

Heather Dean, 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

Indications for Use

510(k) Number (if known)

K210448

Device Name

adhesive electrode

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 stimulator, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).

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

I Submitter

510(K) Number: K210448
Device submitter: Shaoxing Yingtuo Healthcare Co.,Ltd.
NO.176 Shungeng Road, Baiguan Street, Shangyu
Area, Shaoxing City, Zhejiang Province, P.R. CHINA.

Contact person: Haze XU
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II Device

Trade Name of Device: adhesive electrode
Common name: Cutaneous Electrode
Classification: Class II, 21 CFR 882.1320
Product Code: GXY

III Predicate Device

Trade name: TENS Electrodes
Common name: Cutaneous Electrode
Classification: Class II, 21 CFR 882.1320
Product Code: GXY
Premarket Notification: K160081
Company name: CATHAY MANUFACTURING CORP.

IV Device description

The adhesive electrode is placed onto human skin and connected with electrical stimulators by lead wires. The electrical pulses are passed across the intact surface of the skin to activate the underlying nerves.

V 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).

VI Comparison of technological characteristics with the predicate devices

The adhesive electrode has the same intended use and principle operation, the technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the adhesive electrode and predicate devices do not alter suitability of the proposed device for its intended use.

Device feature	adhesive electrode (subject device)	TENS Electrodes K160081 (predicate device)	Discussion
Intended use	<p>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).</p>	<p>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</p>	Substantially equivalent.
Surface area	<p>(Length * width): 20mm*40mm, 22mm*22mm 25mm*35mm, 25mm*42mm 25mm*60mm, 30mm*40mm 30mm*50mm, 30mm*60mm 30mm*70mm, 32mm*32mm 40mm*40mm, 40mm*50mm 40mm*60mm, 40mm*70mm 40mm*80mm, 40mm*90mm 40mm*100mm, 40mm*110mm, 40mm*120mm, 40mm*130mm, 45mm*45mm, 45mm*55mm 45mm*60mm, 45mm*70mm 45mm*80mm, 45mm*90mm 45mm*100mm, 48mm*48mm 48mm*86mm, 50mm*50mm 50mm*60mm, 50mm*70mm 50mm*80mm, 50mm*90mm 50mm*100mm, 50mm*110mm 50mm*120mm, 50mm*130mm 55mm*55mm, 55mm*65mm 55mm*70mm, 55mm*75mm 55mm*80mm, 55mm*90mm 55mm*100mm, 55mm*110mm</p>	<p>Largest model: CM100180FC (Rectangle shape: 100 x 180 mm); Smallest model: CM2222FC(square shape: 22 x 22 mm); Irregular representative: CM2542YC(crescent);</p>	Substantially equivalent. The surface area of the device does not alter its intended use.

Device feature	adhesive electrode (subject device)	TENS Electrodes K160081 (predicate device)	Discussion
	55mm*120mm, 55mm*130mm 60mm*60mm, 60mm*70mm 60mm*80mm, 60mm*90mm 60mm*100mm, 60mm*110mm 60mm*120mm, 60mm*130mm 65mm*65mm, 70mm*70mm 70mm*80mm, 70mm*90mm 70mm*100mm, 70mm*110mm 70mm*120mm, 70mm*130mm 75mm*75mm, 75mm*125mm 80mm*80mm, 80mm*100mm 80mm*110mm, 80mm*120mm 80mm*130mm, 85mm*85mm 85mm*180mm, 90mm*90mm 90mm*120mm, 90mm*130mm 100mm*120mm, 100mm*125mm 100mm*130mm, 100mm*140mm 100mm*180mm, 105mm*155mm 124mm*130mm. (Diameter): 22mm, 25mm, 32mm, 40mm, 45mm, 50mm, 55mm, 60mm, 65mm, 70mm, 75mm, 80mm, 85mm, 90mm		
Components	Substrate/Wire/Hydrogel/Scrim/Conductive Fiber/Carbon conductive film/Liner	Substrate/Wire/Hydro-gel/Scrim/Conductive Fiber/Carbon conductive film/Liner	Identical
Materials	Non-woven Fabric + Adhesive	Non-woven Fabric + Adhesive	Identical
	Wire and Terminal coated PVC	Wire and Terminal coated PVC	Identical
	Hydrogel	Hydro-gel	Identical
	PET Fabric	PET Fabric	Identical
	Carbon fiber + Reinforcing fiber	Carbon fiber + Reinforcing fiber	Identical
	Poly-isobutylene, Carbon Black,	Poly-isobutylene, Carbon	Substantially

Device feature	adhesive electrode (subject device)	TENS Electrodes K160081 (predicate device)	Discussion
	Graphite, Additives	Black	equivalent.
Current(mA _{rms})	58.81	Not Publicly Available	/
Charge(μC)	17.40	Not Publicly Available	/
power densities(mW/mm ²)	448.32	Not Publicly Available	/
Biocompatibility	Comply with ISO 10993 series	Comply with ISO 10993 series	Identical
Sterility	Non-sterile	Non-sterile	Identical
Re-usable	For single patient	For single patient	Identical
Shelf life	3 years	2 years	Substantially equivalent.

VII Summary of Non-clinical tests:

Biocompatibility testing

Biocompatibility of the adhesive electrode was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “Surface-contacting devices: Skin” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Sensitization. All evaluation acceptance criteria were met.

Shelf life testing

The shelf life of the adhesive electrode is determined based on stability study which includes ageing test.

Product performance testing

Performance testing includes pull test, conformability test, fluid tolerance test, impedance testing, and Shelf-Life testing for both subject device and predicate device.

VIII Conclusion

The adhesive electrode is substantially equivalent to its predicate devices. The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as the legally marketed device.