January 15, 2025

ShenZhen Deliduo Medical Technology Co., Ltd
℅ Wu Jarvis
Senior Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
14th Floor, Dongfang Building, 1500# Century Ave.
Shanghai, Shanghai 200122
China

Re: K241512
Trade/Device Name: Electrode Pad
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 10, 2025
Received: January 10, 2025

Dear Wu Jarvis:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241512

Device Name

Electrode Pad

Indications for Use *(Describe)*

It is is intended to transmit electrical current to patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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ShenZhen Deliduo Medical Technology Co.,Ltd.
B1406, 14th Floor, Block B, Fenglin International Center, Building 3,Hongji Garden, Zhongcheng District 4, Jixiang Community, Longcheng Street, Longgang District, Shenzhen City, Guangdong China 518116

510(k) Summary

K241512

1. Applicant Information:

ShenZhen Deliduo Medical Technology Co.,Ltd.
Address:
B1406, 14th Floor, Block B, Fenglin International Center, Building 3,Hongji Garden, Zhongcheng District 4, Jixiang Community, Longcheng Street, Longgang District, Shen zhen City, Guangdong China 518116
Contact Person: Andy Liu
Tel: +86- 13728752377

Prepared date: January 9th,2025

2. Device information

Trade Name：Electrode Pad
Common Name: Cutaneous electrode
Classification name: Cutaneous electrode
Regulation Number: 882.1320
Product code: GXY

3. Predicate device

K182111
DL Adhesive Electrode
SHAOXING DL HEALTHCARE CO., LTD.

4. Indication for use

The Electrode Pad is intended to transmit electrical current to patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The -Counter) or Prescription use.

5. Device description

Electrode Pad is used as an accessory to the TENS or EMS device unit, which transmits electrical current to patient skin. The electrical current of Electrode Pad is first transmitted via the snap button or lead wire then transmitted to the conductive gel which is adhered to patient skin.
Electrode Pad is composed of a top cover, connector snap button or lead wire, conductive carbon film, conductive hydrogel media, and a carrier liner. The carrier liner is made of PET (polyethylene terephthalate).
Electrode Pad is non-sterile and intended for single adult patient multiple application use. The electrode pad has various shapes and sizes.

6. Comparison of the device character

	Subject Device (K241512)	Predicate Device (K182111)	Comparison
Trade Name	Electrode Pad	DL Adhesive Electrode	N/A
Common Name	Cutaneous electrode	Cutaneous electrode	Same
Classification name	Cutaneous electrode	Cutaneous electrode	Same
Product Code	GXY	GXY	Same
Regulation Number	882.1320	882.1320	Same
Medical Specialty	Neurology	Neurology	Same
Device Class	II	II	Same
Indications for use	The Electrode Pad is intended to transmit electrical current to patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The -Counter) or Prescription use.	DL Adhesive Electrode is intended to transmit electrical current to patient skin for use with transcutaneous electrical stimulation devices. Some common types of the stimulation devices include, but are not limited to TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). The electrode is for OTC (Over-The-Counter) or Prescription use.	Same
Target population	Single patient use and multiple application	Single patient use and multiple application	Same
Prescription use	OTC and Prescription use	OTC and Prescription use	Same
Design (shape &Connection)	Electrode Pad: rectangle, square, according to customized specification. Lead wire with female socket, or snap button with male snap connector	Electrode Pad: Round, rectangle, butterfly, oval, according to customized specification. Lead wire with female socket, or snap button with male snap connector	Similar
Materials	- Top cover material - Electrically conductive carbon cloth - Biocompatible conductive	- Top cover material - Electrically conductive carbon cloth - Biocompatible conductive	Same

	hydrogel - Protective film （Electrode carrier liner）	hydrogel - Electrode carrier liner	
Electrode Pad Size	Rectangle: 50*100mm	Rectangle: 40*40mm~40*350mm	Different*1
		Butterfly: 3*150mm~110*150mm	
	Square: 50*50mm	Round: Ø18mm~ Ø85mm	
		Oval: 50*78mm	
Patient contact area of Electrode Pad	Rectangle: 5000mm^2	Round: 254.34mm^2~5671.63mm^2	Different*1
		Rectangle:1600m m2~7000mm2	
	Square: 2500mm^2	Oval:3900mm2	
		Butterfly:6975mm2~8250mm2	
Hydrogel thickness	0.75±0.15mm	1.0mm±0.2mm	Similar
Electrode Impedance testing	426-635Ω	415-688Ω	Similar
Conductive carbon film	PU/PE conductive film,	PU, Conductive carbon	Similar
Shelf life	2 years	2 years	Same
Stainless Steel Adhesion (180° peel)	136 grams minimum(≈1.3N)	136 grams minimum(≈1.3N)	Same
Biocompatibility	ISO10993-5:2009; ISO10993-10:2010	ISO10993-5:2009; ISO10993-10:2010	Same
Sterilization	Non-sterile	Non-sterile	Same
Electrical safety	Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1: 2005/(R)2012 And A1:2012	Lead wire meets Clause 8.5.2.3 of AAMI/ANSI ES60601-1: 2005/(R)2012 And A1:2012	Same

Difference*1 analysis:

The devices' size difference causes the Patient contact area difference, the difference will not raise any new risk of effectiveness or safety issues. The subject devices pass the Electrical safety and Impedance testing.

7. Non-Clinical Test Conclusion

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

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ASTM F1980-16, Standard guide for accelerated aging of sterile barrier systems for medical devices.
- Peel strength testing(180° stainless steel peel)
- Impedance test per ANSI AAMI IEC 60601-2-2
- Lead wires test per AAMI/ANSI ES 60601-1

8. Clinical Test

None.

9. The Conclusions:

Based on successful biocompatibility testing of devices, the electrical performance of the insulated lead wire components and Impedance testing, Adhesive Electrode is safe and effective when used as an interface between a user's skin and an approved nerve and muscle stimulation device. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus the subject device is substantially equivalent to the predicate devices under K182111.