March 24, 2023

Shenzhen Xingyuanli Technology Co., Ltd.
Tse Adrian
Quality manager
4/F, No.1, TianShiDa Industrial Park, No.79 Longwo Road,
Kengzi Street, Pingshan New District
Zhezhen, Guandong 518110
China

Re: K221589
Trade/Device Name: Starly pad
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: June 1, 2022
Received: June 1, 2022

Dear Tse Adrian:

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

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221589

Device Name
Starly pad

Indications for Use *(Describe)*
Starly 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 Starly pad is for OTC (Over-The-Counter) or Prescription use. The Starly 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.

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

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510(k) Summary

1.1 Submitter Information

- Company: Shenzhen Xingyuanli Technology Co., Ltd.
- Address: 4/F, No.1, TianShiDa Industrial Park, No.79 Longwo Road, Kengzi street, Pingshan New District, Shenzhen.
- Phone: +086-15915873605
- Contact: Tse Adrian, Quality Manager
- Mail box: xkxadrian@gmail.com
- Date Prepared: Feb. 20, 2023

1.2 Device Information

- Trade/Device Name: Starly pad
- Common Name: Cutaneous electrode
- Classification regulation:
  Regulation number: 21 CFR 882.1320
  Regulation Description: Cutaneous electrode.
  Regulation Medical Specialty: Neurology
- Review Panel: Neurology
- Product Code: GXY
- Regulation Number: 21 CFR 882.1320
- Device Class: Class II
- Submission number: K221589
- Biocompatibility information: Contact duration categorization of the Starly Pad is Classification B of Intact skin (prolonged - 24h to 30 d); The device is intended for prolonged use over a maximum period of 30 days.

1.3 Predicate Device Information

Predicate Device: ELECTRODES PAD

Manufacturer: Shenzhen Bestpad Technology Development Co., Ltd

510(k) number: K190700

Indication of 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 ELECTRODES PAD is for OTC (Over-The-Counter) or Prescription use. The ELECTRODES PAD is for adults only.

No reference devices were used in this submission.

1.4 Subject Device Description

- Device Identification

key device components: The Starly pad consists of Insulation backing layer, Adhesive layer, Conducting film, Gel layer, Protective film and Snap fastener.

Fig 1. Entity diagram

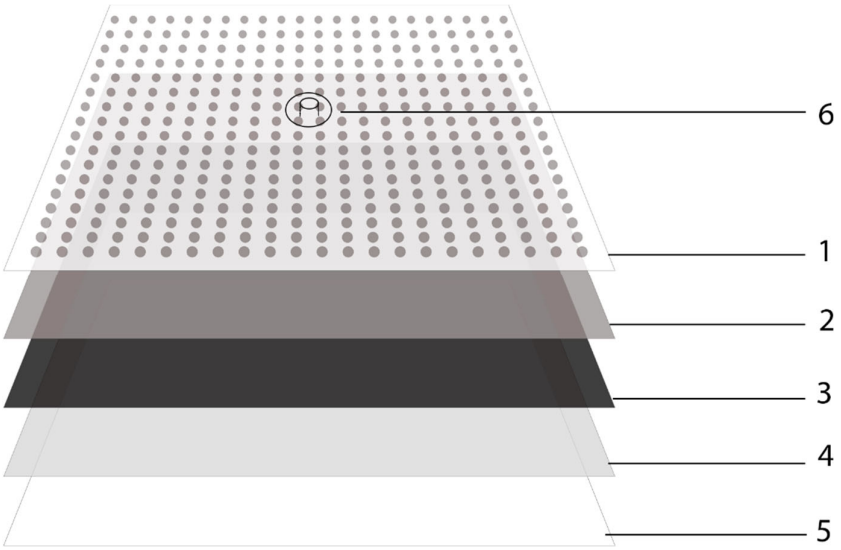

Fig 2. Structure diagram

No.	Name	Description
1	Insulation backing layer	Insulate current to prevent current leakage
2	Adhesive layer	Connect the insulation backing layer and carbon film layer
3	Carbon film	Conduct and distribute treatment current to next layer
4	Conductive adhesive piece layer	Conduct treatment current to patient
5	Protective film	Prevent medical adhesive from sticking to dust
6	Snap fastener	Connect with therapeutic device that releases an electric current

- Device Characteristics

Patient-contacting material: Conductive adhesive piece layer (Medical conductive gel)

Sterile: The Starly Pad is not supplied sterile and do not require sterilization prior to use.

- Environment of Use:

Healthcare facility/hospital or,

Home.

- Intended user:

Adult only.

- Brief Written Description of the Device:

Principle of operation: Through the electrical conductivity of the material, the current connected to the device is transmitted steadily to the skin surface of the human body.

Mechanism of action: It's allowed electrical stimulation signal output from electrotherapy device is transmitted to the human body through conductive materials of the Starly Pad.

- Materials of Use

General type of material used: Nonwovens-Polypropylene and Poly(ethylene)

Duration and type of contact: Classification B of Intact skin (prolonged - 24h to 30 d);

- Key Performance Specifications/Characteristics of the Device:

Impedance	100-300Ω
Skin adhesion performance	30 times

1.5 Indications for Use

Starly 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 Starly pad is for OTC (Over-The-Counter) or Prescription use. The Starly pad is for adults only.

1.6 Comparison of Technological Characteristics with the Predicate Device

Comparison Items	Subject Device: Starly pad	Predicate Device: Electrodes pad (K190700)
Classification & Intended Use		
Classification	GXY Class II 21 CFR 882.1320	GXY Class II 21 CFR 882.1320
Classification name	Cutaneous electrode	Cutaneous electrode
Intended use	Starly 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 Starly pad is for OTC (Over-The-Counter) or Prescription use. The Starly pad is for adults only.	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.
Environment of Use	For OTC (Over-The-Counter) or Prescription use.	For OTC (Over-The-Counter) or Prescription use.
Contraindications	People allergic to this ingredient are not allowed. Contraindicated on skin	People allergic to this ingredient are not allowed. Contraindicated on skin

	wounds.	wounds.
Comparison Statement	The subject device enjoys the same classification and intended use with the predicate device.	
Technological Characteristics		
Principle / Method of Operation	Through the electrical conductivity of the material, the current connected to the device is transmitted steadily to the skin surface of the human body.	Through the electrical conductivity of the material, the current connected to the device is transmitted steadily to the skin surface of the human body.
Structural composition	Starly pad consists of nonwovens, conductive adhesive piece, PET film and fastener.	It composed of an insulation backing layer, a double sides adhesive tape, conducting film, hydrogel and plastic film.
Shapes	Square flake	Square flake
Dimension	Thickness: 2.0mm±0.5mm Width: 20 mm~300 mm (integers specification only, ±0.5mm) Length: 20 mm~300 mm (integers specification only, ±0.5mm)	(mm) Length: 20~300 Width: 20~300 Height (thickness): 1~20
Impedance	100-300Ω	<300Ω
Skin adhesion performance	30 times	30 times
Sterility status	Non-sterile	Non-sterile
Reusable or Disposable?	Reusable	Reusable
Shelf life (Storage	2 years	2 years

life)		
Single patient use?	Yes	Yes
Self-adhesive	Self-adhesive	Self-adhesive
Connection type	Snap fastener	Snap fastener or plug wire
Comparison statement	Dimension, Impedance and Connection type is different	
Safety & Effectiveness		
Patient contacting material	Conductive adhesive piece layer which made of Medical conductive gel	Hydrogel
Biocompatibility	ISO 10993-5	Complied with ISO 10993
	ISO 10993-10	Complied with ISO 10993
Comparison statement	The safety and essential effectiveness of the subject device have been evaluated according to the FDA recognized standards.	

1.6.1 Comparison summary

1. Is the predicate device legally marketed?

The predicate device is the **Electrodes pad**, manufactured by Shenzhen Bestpad Technology Development Co., LTD, and the 510(k) number is K190700.

The predicate device is legally marketed.

2. Do the devices have the same intended use?

From the comparison in this section, the subject device (Starly pad) has same intended use with the predicate device. The labeling of the predicate device is consistent with its IFU statements.

The subject device and the predicate device have the same intended use.

3. Do the devices have the same technological characteristics?

Dimension, Impedance and Connection type are different.

4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?

Determine what questions of safety and effectiveness the different technological characteristics raise:

- Dimension

The dimension specification of the subject device is included in the dimension specification of the predicate device; the length and width of the subject device are the same as the predicate device, but more specific integer value requirements are defined; the thickness of the predicate device is usually customized by the customer, and the thickness of the subject device Fixed to 2.0mm; And key properties such as Impedance and Skin adhesion performance are not directly related to the thickness; this difference does not affect the safety and effectiveness.

- Impedance

If the impedance is too low, the excessive current might will be conducted through the pad. If the impedance is too high, the current will not able to conducted through the pad. The Impedance specification of the subject device is included in the Impedance specification of the predicate device; the subject device limits the minimum impedance value, which reduces the possibility of excessive current and improves safety; So there is No questions of safety and effectiveness the different impedance raise.

- Connection type

The difference in Connection type only affects the models of electrical stimulation devices that can be connected, and does not affect the key performance and safety of use.

No questions of safety and effectiveness the different technological characteristics raise.

5. Are the methods acceptable?

Test methods in the 031_Performance test report is scientific and clear.

6. Do the data demonstrate substantial equivalence?

The 031_Performance test report provide scientific methods for evaluating different characteristics' effects on safety and effectiveness. Provided data evidence for substantial equivalence by confirming that the performance parameters of the subject device are consistent with the stated data.

Conclusion:

Substantial equivalence. In respects of Safety & effectiveness, there is no data provided on the biocompatibility. But the subject device had verified the biocompatibility and the test report is attached in Attachment F.

1.7 Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Starly pad was 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 testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

The Starly pad is considered tissue contacting for a duration of more than 24 hours and less than 30 days.

The test report and its reference is below:

Standard Designation Number	Title of Standard	Report

			number
Biocompatibility	ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	SSMT-R-2021-01116-01A
	ISO 10993-10: 2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	SSMT-R-2021-01116-03A SSMT-R-2021-01116-02A

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The Starly pad not composed with any energy storage components and electronic components.

Software Verification and Validation Testing

Not applicable. The Starly pad not composed with any software.

Performance testing

The Starly pad had tested below performance refer to the Performance test report.

Test item	Test report	Test result
Dimensions	Starly Pad Performance Test Report	Thickness: 2.0mm ± 0.5 mm Width: 20 mm~300 mm (integers specification only, ±0.5) Length: 20 mm~300 mm (integers specification only, ±0.5)
Impedance		100-300Ω
Skin adhesion performance		30 times
Shelf life (Storage life)		2 years
Current Dispersion		<10%

Animal Study

Animal Study was not performed for the Starly pad as part of the submission.

Clinical Test

Clinical testing was not performed for the Starly pad as part of the submission.

1.8 Conclusion

From the above analysis, it is proper to conclude that the subject device (Starly pad) will be as safe and effective for usage as the listed predicate devices that have already been on the U.S. market.