May 1, 2026

Dongguan Tutamen Metalwork Co., Ltd.
% Caitlyn Dzhafarov
Regulatory Consultant
Medical Devices Pathway LLC
14330 178th Ln NE
Woodinville, Washington 98072

Re: K252439
Trade/Device Name: Tutamen Self Adhesive Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 3, 2025
Received: August 4, 2025

Dear Caitlyn Dzhafarov:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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)*
K252439

Device Name
Tutamen Self Adhesive Electrodes (Models: SAE003, SAE004)

Indications for Use *(Describe)*

The Self-Adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS

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. Submission Information

510(k) Number: K252439
Date Prepared: May 1, 2026
Type of 510(k) Submission: Traditional 510(k)

2. Submitter / Applicant

Dongguan Tutamen Metalwork Co., LTD.
No.3, Huangguotang Road Tangxia Town DongGuan 523000 China
760-402-7859
Mr. Stephen Prior
stephenprior@tutamen.net

3. Device Identification

Trade / Device Name: Tutamen Self-Adhesive Electrodes
Common Name: Self-adhesive electrode
Classification Name: Cutaneous Electrode
Classification Regulation: 21 CFR 882.1320
Product Code: GXY
Regulatory Class: Class II
Models: SAE003 (Rectangle 2×4"), SAE004 (Round 2")

4. Predicate Device

Predicate 510(k) Number: K213879
Predicate Trade Name: Self-Adhesive Electrode
Predicate Manufacturer: Bozhou Rongjian Medical Appliance Co., Ltd.
Predicate Clearance Date: January 5, 2022

5. Device Description

The Self-adhesive electrode, lead wire type, is a non-sterile flexible structure composed of commonly used materials in electrode devices.

The electrodes are designed for single patient / single application use. It can be used for low-frequency or medium-frequency nerve or muscle stimulators, as the conduction film adhered to body skin.

There are two shapes: round (circle) and rectangle. For the electrical connection, a lead wire type is used.

The conductive hydrogel of the Self-Adhesive Electrode(Hydrogel MH051) is manufactured by Shaoxing Jingqi Medical Co., Ltd. (a subsidiary of TOP-RANK Healthcare Co., Ltd.).

6. Indications for Use

The Self-adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.

7. Indications for Use Comparison

Table 1 provides a comparison of the technological characteristics of the Tutamen Self-Adhesive Electrodes (subject device) and the Bozhou Self-Adhesive Electrode (predicate device, K213879). Where differences exist, scientific justification is provided to demonstrate that the difference does not raise new or different questions of safety or effectiveness.

Table 1. Substantial Equivalence Comparison

Feature	Tutamen Self-Adhesive Electrodes (Subject Device)	Bozhou Self-Adhesive Electrode (Predicate Device, K213879)	Substantial Equivalence Comments
Product Code, Classification	GXY 21 CFR 882.1320 Cutaneous Electrode, Class II	GXY 21 CFR 882.1320 Cutaneous Electrode, Class II	Same
Indications for Use	The Self-adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.	The Self-adhesive Electrode is intended to be used to transmit electrical stimulation current to the patient's skin. Example electrical stimulations for current applications of the electrodes are: TENS and EMS.	Same.
Rx / OTC	OTC and Prescription (Rx)	OTC and Prescription (Rx)	Same
Number of Uses	Single patient use, single application use (Do not reuse)	Single patient use, multiple application use	Similar. The subject device is labelled for single-application use. This difference reduces (does not increase) potential risks of between-use degradation of adhesive integrity and cross-contamination. The difference does not raise new or different questions of safety or effectiveness.
Design (Connection)	Conductive carbon cloth electrode laminated with conductive hydrogel and non-woven fabric backing. Electrodes incorporate a fixed lead wire terminated in a 2 mm pigtail pin connector for attachment to compatible electrical stimulation devices.	Lead wire with female socket, or snap button with male snap connector.	Similar. The subject device is constructed of conductive carbon cloth laminated with conductive hydrogel and non-woven fabric backing — the same fundamental construction as the predicate. The subject device employs a fixed lead wire terminated in a 2 mm pigtail pin connector. The 2 mm pin connector is widely used in cleared TENS / EMS electrodes. Differences in connector configuration do not affect electrical performance, intended use, or safety.
Design (Geometry)	Round (circle) and rectangle	Round, Rectangle, Elliptical, Calabash, Butterfly, Palm shape according to customized specification	Similar. The subject device offers two of the predicate's listed shapes (Round and Rectangle).
Materials	• Non-woven fabric tape • Electrically conductive carbon cloth • Biocompatible conductive hydrogel (Hydrogel MH051,	• Non-woven fabric tape • Polyurethane (PU) electrically conductive carbon cloth (Hebei Kangshengda Electronic Technology Co., Ltd.)	Similar. Both devices use electrically conductive carbon cloth and a biocompatible conductive hydrogel as patient-contacting materials. All patient-contacting materials of the subject device have been evaluated per ISO 10993-1, including ISO 10993-5

Feature	Tutamen Self-Adhesive Electrodes (Subject Device)	Bozhou Self-Adhesive Electrode (Predicate Device, K213879)	Substantial Equivalence Comments
	Shaoxing Jingqi Medical Co., Ltd.)	• Biocompatible conductive hydrogel coupling media (ValueTrode Carbon, referenced 510(k) K970426)	(cytotoxicity), ISO 10993-10 (sensitization), and ISO 10993-23 (irritation). Differences in carbon cloth substrate and hydrogel supplier do not raise new or different questions of safety or effectiveness given the equivalent materials and the supporting biocompatibility evaluation.
Electrode Pad Size — Round	Ø50 mm (single size)	Min. Ø20 mm; Max. Ø85 mm (range)	Similar. Within range. The subject device's single round size (Ø50 mm) falls within the predicate's reported range (Ø20–85 mm).
Electrode Pad Size — Rectangle	50 × 100 mm (single size)	Min. 26 × 26 mm; Max. 190 × 110 mm (range)	Similar. Within range. The subject device's single rectangular size (50 × 100 mm) falls within the predicate's reported rectangular size range.
Patient Contact Area — Round	19.6 cm² (Ø50 mm; single size)	Min. 3.14 cm²; Max. 56.716 cm² (range)	Similar. Within range. The subject device's round contact area is within the predicate's reported range.
Patient Contact Area — Rectangle	50.0 cm² (50 × 100 mm; single size)	Min. 6.76 cm²; Max. 209 cm² (range)	Similar. Within range. The subject device's rectangular contact area is within the predicate's reported range.
Maximum Current Density of Electrode (calculated using IRMS = 10 mA)	Round (19.6 cm²): 0.51 mA/cm² • Rectangle (50.0 cm²): 0.20 mA/cm²	Round (Ø20 mm; 3.14 cm²): 3.18 mA/cm² • Rectangle (26 × 26 mm; 6.76 cm²): 1.48 mA/cm² • Elliptical (85 × 45 mm/2; 19.13 cm²): 0.52 mA/cm² • Calabash (90 × 47 mm; 42.3 cm²): 0.24 mA/cm² • Butterfly (73 × 53 mm/2; 19.35 cm²): 0.52 mA/cm² • Palm (74 × 47 mm; 34.78 cm²): 0.29 mA/cm²	Similar. The subject device's maximum calculated current density is 0.51 mA/cm² (round Ø50 mm), which is within the range of the predicate 0.29-3.18 mA/cm². The rectangle has similar maximum current density as predicate, though slightly lower. The differences do not raise new or different questions of safety or effectiveness.
Electrode Impedance of Electrode Pad	At 1 kHz: Round: 509-573 Ω Rectangle: 513-599 Ω At 10 Hz: Round: 1520-1786 Ω Rectangle: 1310-1910 Ω	Round 302–577 Ω; Rectangle 303–646 Ω; Elliptical 407–676 Ω; Calabash 401–602 Ω; Butterfly 402–626 Ω; Palm 402–638 Ω	Similar. Measured 1 kHz impedance for the subject device falls within the predicate's reported range for comparable geometries (frequency not reported in public 510(K) Summary).
Hydrogel Thickness	1.8 mm ± 0.15 mm	0.89 mm ± 0.13 mm (35 mils ± 5 mils)	Similar. The subject device uses a thicker hydrogel layer, which provides additional adhesive cushioning. Thicker hydrogel does not introduce a new mechanism of action or raise new biocompatibility concerns.
Hydrogel pH	5.8 ± 0.4	4.2 ± 1.0	Similar. Subject device biocompatibility was evaluated per ISO 10993-5 (cytotoxicity), ISO 10993-10 (sensitization), and ISO 10993-23 (irritation) on final, finished electrodes;

Feature	Tutamen Self-Adhesive Electrodes (Subject Device)	Bozhou Self-Adhesive Electrode (Predicate Device, K213879)	Substantial Equivalence Comments
			results were non-cytotoxic, non-irritating, and non-sensitizing.
Sterility	Non-sterile	Non-sterile	Same
Shelf Life	2 years	Not specified in 510(k) Summary	Subject device labelled shelf life is supported by 2-year real-time aged performance testing.

8. Discussion of Differences

8.1 Number of Uses (Single-Application)

The subject device is labelled for single-patient, single-application use; the predicate is labelled for single-patient, multiple-application use. Single-application labelling eliminates between-use storage and adhesive degradation considerations due to re-use. The difference does not introduce a new mechanism of action or new patient-contact concern relative to the predicate, and therefore does not raise new or different questions of safety or effectiveness.

8.2 Electrode Geometries Offered

The subject device is offered in two (2) geometries (round and rectangle); the predicate offers six (6) geometries. Both subject device sizes fall within the patient contact area and dimensional ranges of the predicate. Reduction in number of available geometries does not affect intended use, mechanism of action, or fundamental electrical performance.

8.3 Connector Configuration

The subject device employs a fixed lead wire terminated in a 2 mm pigtail pin connector. The 2 mm pin connector is widely used across cleared TENS / EMS electrodes.

8.4 Hydrogel Material

The subject device hydrogel is Hydrogel MH051 manufactured by Shaoxing Jingqi Medical Co., Ltd.. Both the subject and predicate hydrogels serve the same functional role (biocompatible conductive material between carbon cloth and skin) and are similar material composition. Subject device biocompatibility was evaluated per ISO 10993-5, ISO 10993-23, and ISO 10993-10, on final, finished electrodes; the device was demonstrated to be non-cytotoxic, non-irritating, and non-sensitizing.

8.5 Hydrogel Thickness and pH

Subject device hydrogel is 1.8 mm thick (vs. predicate 0.89 mm) — the additional thickness provides adhesive cushioning, with no biocompatibility implications.

8.6 Maximum Current Density

The subject device's maximum calculated current density is 0.51 mA/cm² (round Ø50 mm), which is within the range of the predicate 0.29-3.18 mA/cm². The rectangle has similar maximum current density as predicate, though slightly lower. The differences do not raise new or different questions of safety or effectiveness

8.7 Impedance

Subject device measured 1 kHz impedance (509–599 Ω across both submitted models) is consistent with the predicate's reported range (302–676 Ω; tested frequency not specified in 510(K) Summary). Two-year real-time aged impedance testing demonstrated long-term electrical stability.

9. Non-Clinical Performance Testing

The following non-clinical bench testing was conducted to support the substantial equivalence determination. All testing was performed on production-equivalent samples.

- Electrode impedance testing
- Adhesive strength and electrode integrity testing
- Shelf-Life testing (2 year real-time aged Self-Adhesive Electrodes; impedance, adhesive strength, and electrode integrity testing)
- Biocompatibility testing (ISO 10993-5, ISO 10993-10, ISO 10993-23)

10. Clinical Performance Testing

Clinical testing was not provided to support substantial equivalence. The subject device's intended use, fundamental technology, materials, and performance are substantially equivalent to the legally marketed predicate device (K213879). Non-clinical bench testing and biocompatibility evaluation are sufficient to demonstrate substantial equivalence.

11. Conclusion of Substantial Equivalence

Based on the comparison in Section 7 (Table 1) and the scientific justification provided in Section 8, the Tutamen Self-Adhesive Electrodes have the same intended use as the predicate device (K213879, Bozhou Self-Adhesive Electrode); have substantially equivalent technological characteristics; and where differences exist, those differences do not raise new or different questions of safety or effectiveness. Non-clinical performance testing supports substantial equivalence. The Tutamen Self-Adhesive Electrodes are therefore substantially equivalent to the legally marketed predicate K213879, Bozhou Self-Adhesive Electrode.