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U.S. FOOD & DRUG ADMINISTRATION

April 9, 2025

Transtimulation Research, Inc
c/o Victor Pikov
Vice President of Product Development
800 Research Parkway, # 337
Oklahoma City, Oklahoma 73104

Re: K243613
Trade/Device Name: Patch-TEA (Model TRI-21)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: March 10, 2025
Received: March 10, 2025

Dear Victor Pikov:

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,

PAMELA D. SCOTT -S

Digitally signed by PAMELA D. SCOTT -S
Date: 2025.04.09 15:34:14 -04'00'

Pamela D. Scott
Assistant Director
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)*

K243613

Device Name

Patch-TEA (Model TRI-21)

Indications for Use *(Describe)*

Patch-TEA is an Over-The-Counter device to be used by adults only for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, arm, and leg, due to strain from exercise or normal household work activities and suitable for home 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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510(k) #: K243613

# 510(k) Summary

Prepared on: 2025-04-07

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Transtimulation Research, Inc |
| Applicant Address | 800 Research Parkway, # 337 Oklahoma City OK 73104 United States |
| Applicant Contact Telephone | 626-4979441 |
| Applicant Contact | Victor Pikov |
| Applicant Contact Email | victor@transtimulation.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Patch-TEA (Model TRI-21) |
| Common Name | Transcutaneous electrical nerve stimulator for pain relief |
| Classification Name | Stimulator, Nerve, Transcutaneous, Over-The-Counter |
| Regulation Number | 882.5890 |
| Product Code(s) | NUH |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K212377 | Transcutaneous Electrical Applicator (TEA), Model SNM-FDC01 | NUH |
| K231569 | ManaFlexx 2 (model: MF002-RX, MF002-OTC) | NUH |

## Device Description Summary

21 CFR 807.92(a)(4)

The Patch-TEA device is a non-invasive, battery-operated, over-the-counter transcutaneous electrical nerve field stimulator indicated for use in adult patients for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, arm, and leg, due to strain from exercise or normal household work activities and suitable for home use.
The system includes the following components: Patch-TEA device, charging case, electrode pads, USB charging cable, and Patch-TEA app. The device can be used in clinical environments (i.e., outpatient clinics and hospitals) and/or at home.
The Patch-TEA device is powered by an internal rechargeable lithium polymer battery and uses a microprocessor to control the working modes, the waveform and strength of the output pulse. The electric pulse generator is based on a current source circuit. The power management module contains a DC-DC boost conversion circuit that provides the required voltage for the electric pulse generator. The Patch-TEA device is able to connect with the Patch-TEA app, which is located on a smartphone. The user interface is available on both the Patch-TEA device and Patch-TEA app. The user can power on/off the device, adjust treatment time and treatment intensity. Treatment time is adjustable within the of range 5~240 minutes per treatment session. In addition, there is over-load, over-current and no-load protection as well as an automatic shut-off function. The Bluetooth transceiver module is responsible for communication between the Patch-TEA device and Patch-TEA app located on a smartphone.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Patch-TEA is an Over-The-Counter device to be used by adults only for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, arm, and leg, due to strain from exercise or normal household work activities and suitable for home use.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device and the predicate device have the same indications for use.

## Technological Comparison 21 CFR 807.92(a)(6)

Technical characteristics of the subject device were compared to the predicate and reference devices. Based on that comparison, technical characteristics of the subject device are substantially equivalent to the predicate and reference devices in the following aspects:

- same intended use: indications for use, patient population, treatment areas, use environment;
- same mode of action;
- similar device design: same use of one output channel, same safety features, same use of rechargeable battery, similar size and weight;
- similar electrode design: reusable, round-shaped, use of self-adhesive conductive hydrogel;
- same safety standards: mechanical, electrical, energy delivery, related to home use (IEC 60601-1-11);
- similar output parameters, as shown in the table below (ACD stands for Average Current Density, APD stands for Average Power Density):

| **Output parameter** | **Subject (K243613)** | **Predicate (K212377)** | **Reference (K231569)** | **Subst. Equivalence** |
|---|---|---|---|---|
| Frequency, Hz | 1 to 50 | 1 to 100 | 35 to 100 | Similar |
| Pulse Width, µs | 50 to 750 | 50 to 500 | 107 | Similar |
| Max. Voltage, V | 5 (500), 20 (2k), 55 (10k) | 6.25 (500), 25 (2k), 65 (10k) | 45 (500), 80 (2k), 130 (10k) | Similar to Predicate |
| Max. Current, mA | 10 (500, 2k), 5.5 (10k) | 12.5 (500, 2k), 6.5 (10k) | 90 (500), 40 (2k), 13 (10k) | Similar to Predicate |
| Max. Charge/Phase, µC (500) | 7.5 | 6.25 | 9.6 | Similar |
| Max. ACD, mA/cm2 (500) | 0.95 | 0.49 (0.7” electrode) | 1.70 | Similar |
| Max. APD, mW/cm2 (500) | 4.8 | 3.1 (0.7” electrode) | 0.035 | Similar to Predicate |
| Net Charge/Pulse, µC | 0 | 0 | 0 | Identical |
| Max. Treatment Time, min | 90, adjustable | 240, adjustable | 30 | Similar to Predicate |
| Waveform | Biphasic | Biphasic | Biphasic | Identical |
| Waveform Shape | Rectangular alternating | Rectangular alternating | Rectangular alternating | Identical |
| Power Source | Rechargeable battery | Rechargeable battery | Rechargeable battery | Identical |
| Patient Leakage Current | N/A (Battery operated ) | N/A (Battery operated) | N/A (Battery operated) | Identical |
| Automatic Shut off? | Yes | Yes | Yes | Identical |
| Automatic Overload Trip? | Yes | Yes | No | Identical to Predicate |
| Automatic Over- current Trip? | Yes | Yes | N/A | Identical to Predicate |
| Automatic No-load Trip? | Yes | Yes | Yes | Identical |

Waveform parameters of the subject device were successfully tested according to the FDA guidance documents and the requirements of IEC 60601-2-10;

The differences between the subject device and the predicate device mainly include the following:

- The battery capacity of the subject device is smaller than that of the predicate device. The subject device battery has passed the IEC 62133-2 test, so this difference does not lead to safety and effectiveness concerns.
- The electrode dimensions of the subject device are a little smaller than those of the predicate device. These differences also do not adversely impact safety or effectiveness in activating the nerve, as the safety and effectiveness are primarily defined by similar maximal average current density and maximal average power density applied to these electrodes. Therefore, difference in the electrode dimensions does not raise any safety or effectiveness issues.

These differences do not raise new issues of safety or effectiveness, and are acceptable based on the benefit-risk assessment.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Verification and validation testing data and acceptance criteria are equivalent to the predicate device in support of the intended use. Non-clinical testing included an evaluation of performance; biocompatibility; EMC; electrical, mechanical, and thermal safety; software verification and validation testing, cybersecurity testing, and design validation testing. Verification and validation testing have demonstrated compliance of Patch-TEA device to the following standards:

- ANSI/AAMI/IEC 62304:2006+A1:2016 Medical device software - Software life cycle processes (FDA Recog. Number 13-79)
- ANSI/AAMI SW96:2023 (FDA Recog. Number 13-131)
- AAMI TIR57:2016 Principles for medical device security - Risk management (FDA Recog. Number 13-83)
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -

nerve and muscle stimulators (FDA Recog. Number 17-16)
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes. Part 2: Lithium systems (FDA Recog. Number 19-33)
- ANSI/AAMI/ISO 14971: 2019 Medical Devices - Application Of Risk Management To Medical Devices (FDA Recog. Number 5-125)
- IEC 60601-1-6: 2020: Medical electrical equipment. Part 1-6. General requirements for basic safety and essential performance - Collateral standard: Usability (FDA Recog. Number 5-132)
- ANSI/AAMI/ISO 10993-5:2009/(R)2014: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (FDA Recog. Number 2-245)
- ANSI/AAMI/ISO 10993-10:2010/(R)2014: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (FDA Recog. Number 2-174)
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation (FDA Recog. Number 2-291)
- FDA Guidance on Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- FCC 47 CFR Part 15 Subpart C: Radio Frequency Devices: Intentional Radiators

The subject device has the same principle of operation and indication for use and similar technological characteristics as the predicate. Any differences identified in the technological characteristics do not raise any issues of safety or effectiveness.
Non-clinical testing demonstrated that subject device has equivalent performance and safety to the predicate device and provided performance and safety data indicating compliance with the standards.
We therefore consider the subject device to be substantially equivalent to the predicate device.