September 14, 2022

Fast Track Technologies, Inc.
% Michael Tomasovich
Sr. Regulatory Affairs Manager
Regulatory Affairs Associates, LLC.
4761 Tara Court
West Bloomfield, Michigan 48323

Re: K212618
Trade/Device Name: iRelieve Microcurrent Pain Relief System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: August 10, 2022
Received: August 11, 2022

Dear Michael Tomasovich:

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,

Amber Ballard, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212618

Device Name
iRelieve Microcurrent Pain Relief System

Indications for Use *(Describe)*
The iRelieve Microcurrent Pain Relief System is intended to be used by physicians or licensed practitioners for symptomatic relief of chronic intractable pain.

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

[as required by section 807.92(c)]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

General Information

Submitted by:	Fast Track Technologies, Inc. 4400 MacArthur Boulevard, Ninth Floor PO Box 7849 Newport Beach, CA 92658-7849 USA
Contact Person:	Michael Tomasovich, MS RAC Regulatory Affairs Associates, LLC 4761 Tara Court West Bloomfield, MI 48323 Phone: +1 (734) 788-3480 Email: mtomasovich@regaffairs.net
Date Prepared:	September 14, 2022

Device Name

Trade Name:	iRelieve Microcurrent Pain Relief System
Common Name(s):	Electrical nerve stimulator

Classification

Regulation:	21 CFR §882.5890
Class:	Class II
Product Code:	GZJ
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Review Panel:	Neurology

Predicate Device

Predicate – Model 7500 Microcurrent TENS Device, Version MCT-F50	K013167	NewCare Products, LLC.

Device Description

The iRelieve Microcurrent Pain Relief System is a microcurrent TENS device that operates by sending electrical impulses through the skin to the nerves lying directly beneath the skin surface. These impulses help block the body's ability to send a pain message to the brain, thereby reducing the pain sensation. The iRelieve Microcurrent Pain Relief System is a single channel device that produces microampere currents with the selected envelopes, waveforms, frequencies, and polarity, with a maximum voltage of 3.0 volts. It is controlled by analogue electrical parts (voltage regulator, frequency oscillator, multiple resistors, etc.) and a digital microprocessor chip that contains embedded programmed software (firmware) that generates a sequence of current flows and frequencies during the course of a single treatment session. The iRelieve Microcurrent Pain Relief System performs this sequence of current flows without user manipulation or device controls other than switching the device on after application of the device to the electrodes.

Electrodes

The device is snapped onto one of two electrode designs. One is a 1-piece electrode designed for use on the back along the spine. The other electrode is a 2-piece design that can be used on other areas of the body, including joints and extremities.

The electrodes are identical in materials to the electrodes cleared under K070807. Both electrodes are stamped out using a die stamp composed of the same material. Both are manufactured by Pepin Manufacturing, Inc. The only different between the electrodes cleared under K070807 and the electrodes in this submission are shape. Relevant testing including Electrode Dispersion and Impedance Testing, Adhesive Testing, Electrode Cord Pull Testing, Fluid Tolerance Testing, and Conformability Testing was conducted to account for this difference.

Indications

The iRelieve Microcurrent Pain Relief System is intended to be used by physicians or licensed practitioners for symptomatic relief of chronic intractable pain.

Performance Testing

The following performance testing was conducted on the iRelieve Microcurrent Pain Relief System:

- Output Performance
- Micro Current Stimulator Measurements
- Validation of the iRelieve Microcurrent Stimulator Electrodes
- Shelf-life testing
- Packaging testing following ASTM D4169-16
- Output final sequence with Oscilloscope Screen Captures at 500, 2K and 10K Ohms
- Battery use life testing

Biocompatibility testing

Biocompatibility testing was leveraged from electrodes cleared under K070807.

Electromagnetic compatibility (EMC) and electrical safety

Electrical safety and EMC testing were conducted on the iRelieve Microcurrent Pain Relief System. The system complies with the IEC 60601-1 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device is considered to be a Class B level of concern (nonserious injury is possible). IEC 62304 was followed.

Comparison to Predicate Devices

The iRelieve Microcurrent Pain Relief System is substantially equivalent to the Model 7500 Microcurrent TENS Device, Version MCT-F50(K013167).

	Subject Device	Predicate Device
Device Name	iRelieve Microcurrent Pain Relief System	**Model 7500 Microcurrent TENS Device, Version MCT-F50**
510(k) Number	K212618	K013167
Manufacturer	Fast Track Technologies	NewCare Products, LLC.
CFR Reference	21 CFR 882.5890	21 CFR 882.5890
Product Code	GZJ	GZJ
Rx/OTC	Rx only	Rx
Indications for Use	The iRelieve Microcurrent Pain Relief System is intended to be used by physicians or licensed practitioners for symptomatic relief of chronic intractable pain.	The subject device is intended to be used for the symptomatic relief of chronic intractable pain.
Basic Unit Characteristics	Integrated (non-console), detachable, portable	Not publicly available
Components Console	Not applicable	Not publicly available
Power Source	1 Coin Cell Battery (CR2032 / 3V)	Not publicly available
Patient Override Control Method	On/Off button or removing electrodes from skin	Not publicly available
Indicator Display Features	The iRelieve Microcurrent Pain Relief System has a red LED light that is inactive when OFF and blinks when ON.	Not publicly available

User Controls	ON/OFF push button switch	Not publicly available
Software/Firmware Control	Yes	Not publicly available
Interface	Snap attachment to TENS electrodes	Not publicly available
Weight	Without battery: 0.84 oz. (23.7 g) With battery: 0.94 oz. (26.7 g)	Not publicly available
Dimensions	Length: 2.25 inches Width: 2.5 inches Height (thickness): 0.625 inches	Not publicly available
Performance Specifications: Components Console	Not applicable	Not publicly available
Method of line current isolation	Not applicable	Not publicly available
Electrical Type	Not applicable	Not publicly available
Patient Leakage Current - Normal Condition (µA)	Not applicable	Not publicly available
Patient Leakage Current - Single Fault Condition (µA)	Not applicable	Not publicly available
Number of Output Modes	One	Not publicly available
Number of Output Channels	One (1) bipolar output channel	Not publicly available
Synchronous or Alternating	Not applicable	Not publicly available
Method of Channel Isolation	Not applicable	Not publicly available
Regulated Current of Regulated Voltage (output signals only)	Not applicable	Not publicly available
Automatic Overload Trip	Not applicable	Not publicly available
Automatic No-Load Trip	Not applicable	Not publicly available
Automatic Shut Off	No	Not publicly available
Timer Range (minutes)	None	Not publicly available
Electrode area	1- Piece electrode, total 109 cm^2 2- Piece electrode half side 76.5 cm^2, total 153 cm^2	Not publicly available
Housing material	Polycarbonate plastic	Not publicly available

OUTPUT SPECIFICATIONS		
Output Modes	Four (4) Under firmware control, a four-hour routine applies the Modes (DC+, DC-, AC, Off) in a preprogrammed sequence and the routine repeats itself every four hours until removed from the skin or powered off.	Not publicly available
Output Channels	One (1) bipolar output channel	Not publicly available
Output Regulation	Regulated current	Not publicly available
Output Control	Output control is regulated by means of electronic hardware components combined with an embedded microcomputer under firmware control. No user adjustable output current control is provided. Intensity varies between 15uA / 20uA / 25uA / 30uA under firmware control.	Not publicly available
Waveform	DC+, DC-, AC (Square wave)	Not publicly available
Frequency	3-909 Hz (specific preprogrammed frequency sequence)	Not publicly available
Rated DC Output	7.5mV – 15mV DC @ 15-30uA across 500Ω	Not publicly available
Maximum output voltage (±10%)	15 mV @ 500Ω 60 mV @ 2kΩ 300 mV @ 10kΩ	Not publicly available
Maximum output current (±10%)	30 uA @ 500Ω 30 uA @ 2kΩ 30 uA @ 10kΩ	Not publicly available
Pulse Width (µs)	167,000µs to 550µs	Not publicly available
Net Charge @ 500Ω (µC/pulse)	0 µC @ 500Ω	Not publicly available
Maximum Phase Charge (µC)	5.34 µC @ 500Ω	Not publicly available
Maximum Current Density (µA/cm2)	0.39 µA/cm² w smallest electrode	Not publicly available
Maximum Power Density (µW/cm2)	0.0059 µW/cm² w smallest electrode	Not publicly available

Burst Mode (i.e., pulse trains) **a. Pulses per burst** **b. Bursts per second** **c. Burst duration (seconds)** **d. Duty Cycle [Line (b) x Line (c)]**	Not applicable	Not publicly available
On Time	On until removed or inactivated	Not publicly available
Off Time	Off until activated	Not publicly available
Treatment time (min)	On until removed or inactivated	Not publicly available
Output intensity levels	15-30 uA	Not publicly available
Testing Standards	-IEC 60601 1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) -IEC 60601-1-6:2010 (Third Edition) + A1:2013	Not publicly available

Discussion of differences

While the subject device only contains one device model, the predicate device contains three separate models of the device with each model containing different output modes. The subject device is Substantially Equivalent in device output to one of these versions, the Model 7500 Microcurrent TENS Device, Version MCT-F50. The premarket notification provided a device description in sufficient detail to demonstrate substantial equivalence to the predicate device.

Conclusion

The iRelieve Microcurrent Pain Relief System and the predicate device have the same intended use and similar technical characteristics, performance and applications. The information supplied in the full 510(k) application illustrates that the device does not pose any new question of safety or effectiveness. The iRelieve Microcurrent Pain Relief System is substantially equivalent to the predicate device.