May 29, 2020

Firstkind Limited
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K201131
Trade/Device Name: firefly T-2
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX

Dear Sheila Hemeon-Heyer:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 28, 2020. Specifically, FDA is updating this SE Letter 510(k) summary file error as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Dr. Heather Dean, OHT5: Office of Neurological and Physical Medicine Devices, 240-402-9874, Heather.Dean@fda.hhs.gov.

Sincerely,

Heather L. Dean -S

Heather Dean, PhD
Acting Assistant Director, Acute Injury Devices
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

May 28, 2020

Firstkind Limited
% Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions LLC
125 Cherry Lane
Amherst, Massachusetts 01002

Re: K201131
Trade/Device Name: firefly™ T-2
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 28, 2020
Received: April 28, 2020

Dear Sheila Hemeon-Heyer:

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 T. Ballard -S

For Vivek Pinto, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201131

Device Name
firefly™ T-2

Indications for Use *(Describe)*
The firefly™ T-2 is intended for stimulation of healthy muscles in order to improve or facilitate muscle performance. The firefly™ T-2 is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

A. Submitter:

Firstkind Limited
Hawk House
Peregrine Business Park
High Wycombe, UK
HP13 7DL

Contact: Neil Buckley, Head of Quality and Regulatory Affairs
Tel: +44 (0) 845 2222 921
Email: neil.buckley@firstkindmedical.com

B. Date Prepared: May 28, 2020

C. Device Name and Classification Information:

Trade Name:	firefly™ T-2
Common Name:	Powered Muscle Stimulator for Muscle Conditioning
Classification Name:	Stimulator, Muscle Powered
Regulation:	21 CFR 890.5850
Product Code:	NGX
Review Panel:	89**,** Physical Medicine

D. Predicate Device: K134001, firefly™ T-1

E. Device Description:

The firefly™ T-2 Neuromuscular Stimulator (firefly™ T-2) is a disposable, fully integrated unit composed of a constant current pulse generator with embedded software and battery enclosed in an over-molded plastic casing, and a silver electrode with a hydrogel coating that provides a means of attachment of the device and electrical contact with the patient. Two buttons are used to control the On/Off function and increase or decrease the intensity level of the device output, which is achieved through changes in the delivered pulse width. The firefly™ T-2 is applied so that the electrodes lie over the common peroneal nerve behind the knee. Stimulation of the common peroneal nerve causes contraction of the calf muscles through the direct activation of the motor neurons, resulting in increased blood flow.

The stimulus intensity varies with the pulse width, which can be set to one of seven levels for the firefly™ T-2. The asymmetric biphasic waveform results in a net charge of zero to the patient during each pulse cycle. The pulse rate is fixed at a frequency of 1 Hz and is

used to isometrically stimulate the leg and foot muscles with a cadence and energy similar to that of walking.

Electrical contact is made with the patient through a hydrogel layer applied during manufacture to the integrated electrode. The patient contacting materials have been previously tested per the requirements of ISO 10993-1 and shown to be biocompatible for prolonged (up to 30 days) contact with intact skin. There are no separate electrode leads or electrodes.

F. Indications for Use:

The firefly™ T-2 is intended for stimulation of healthy muscles in order to improve or facilitate muscle performance. The firefly™ T-2 is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind.

G. Technical Comparison with the Predicate Device and Discussion of Differences

Parameter	Predicate Device firefly™ T-1 (K134001)	Subject Device firefly™ T-2	Comparison
Use environment	Over-the-counter (non-prescription) use in athletic training facilities or the home.	Over-the-counter (non-prescription) use in athletic training facilities or the home.	Same
Anatomical Sites	The firefly with the embedded electrodes is applied to the posterior aspect of the knee only for stimulation of the peroneal nerve.	The firefly with the embedded electrodes is applied to the posterior aspect of the knee only for stimulation of the peroneal nerve.	Same
Stimulator Parameters			
Power source **-Method of Line Current Isolation**	One CR2032 primary lithium coin cell. Not replaceable by user N/A	One CR2032 primary lithium coin cell. Not replaceable by user N/A	Same
-Patient Leakage Current **-Normal Condition** **-Single Fault Condition**	 < 20μA < 20μA	 < 20μA < 20μA	Same

Parameter	firefly™ T-1	firefly™ T-2	Comparison
Number of output modes	Single mode with seven discrete stimulation settings corresponding to the seven pulse widths.	Single mode with seven discrete stimulation settings corresponding to the seven pulse widths.	Same
Number of output channels / synchronous or alternating?	Single channel N/A	Single channel N/A	Same
-Method of channel isolation	N/A (single channel)	N/A (single channel)	Same
Regulated current or regulated voltage	Current	Current	Same
Microprocessor controlled?	Yes	Yes	Same
Automatic overload trip	Yes	Yes	Same
Automatic no-load trip	Yes	Yes	Same
Automatic shut-off	Yes	Yes	Same
User over-ride control	Yes	Yes	Same
Indicator display: **- On/Off status** **- Low battery** **-Voltage / current level**	 Yes Yes (device switches off) N/A (device has fixed constant current). Stimulus level is indicated by flashing LED.	 Yes Yes (device switches off) N/A (device has fixed constant current). Stimulus level is indicated by flashing LED.	Same
Timer range in minutes	1800 minutes maximum (device is disabled after 30 hours battery run time)	1800 minutes maximum (device is disabled after 30 hours battery run time)	Same
Compliance with voluntary standards	Yes IEC 60601-1:1998 A1, A2 IEC 60601-2-10:1987, A1 EN 60601-1-2:2007 ISO 10993-1:2009	Yes IEC 60601-1:2005 IEC 60601-2-10:2012 EN 60601-1-2:2015 ISO 10993-1:2009	firefly T-2 complies with current recognized versions of applicable standards.
Compliance with 21 CFR 898	N/A (electrodes are integral with the device, there are no separate leads)	N/A (electrodes are integral with the device, there are no separate leads)	Same

Parameter	firefly™ T-1	firefly™ T-2	Comparison
Weight	18 g	10g	firefly T-2 is slightly lighter than T-1.
Dimensions	6” x 1.6” x 0.4”	7.8” x 1.2” x 0.4”	firefly T-2 is slightly longer and narrower than T-1.
Housing material and construction	Plastic injection molding	Plastic injection molding	Same
Waveform Parameters			
Mode or Program Name	N/A, single mode Used for Active Recovery	N/A, single mode Used for Active Recovery	Same
Waveform **- Pulsed monophasic or biphasic** **- Shape**	Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	Same
Maximum output voltage (± 15%)	13.5 V @ 500 Ω 54 V @ 2 kΩ 110 V @ 10 k Ω	14.0 V @ 500 Ω 53.5 V @ 2 kΩ 255 V @ 10 k Ω	Design of firefly T-2 has been improved to maintain desired current output even at high loads.
Maximum output current (± 15%)	27 mA @ 500 Ω 27 mA @ 2 kΩ 11 mA @ 10 kΩ	27.9 mA @ 500 Ω 26.8 mA @ 2 kΩ 25.5 mA @ 10 kΩ	Design of firefly T-2 has been improved to maintain desired current output even at high loads.
Pulse widths	70, 100, 140, 200, 280, 400, 560 µs	50, 70, 100, 140, 200, 280, 400 µs	firefly T-2 pulse widths decreased at each setting to compensate for better current output.
Frequency	1 Hz	1 Hz	Same
For interferential modes only: **-Beat Frequency (Hz)**	N/A	N/A	Same
For multiphasic waveforms only **-Symmetrical phases** **-Phase duration(s)**	No 70-560 µs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant.	No 50-400 µs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant.	Same Same except for reduced pulse duration at each setting for firefly T-2

Parameter	firefly™ T-1	firefly™ T-2	Comparison
Net charge **-How achieved**	0 µC at 500 Ω Capacitor coupling	0 µC at 500 Ω Capacitor coupling	Same Same
Maximum phase charge (@500Ω)	18.3 µC	18.3 µC	Same
Maximum current density (@500Ω)	0.169 mA/cm^2 rms	0.169 mA/cm^2 rms	Same
Maximum avg current (average absolute value), mA (@500Ω)	0.037 mA	0.037 mA	Same
Maximum avg power density (using smallest electrodes) (@500Ω)	0.000044 W/cm^2	0.000044 W/cm^2	Same
Burst mode	N/A, single pulse, no burst mode	N/A, single pulse, no burst mode	Same
ON Time (seconds) / OFF Time (seconds)	N/A Stimulation is continually on or off when power is on or off.	N/A Stimulation is continually on or off when power is on or off.	Same
Electrodes	Two electrodes integrated within the device. A single piece of hydrogel covers the electrodes and the underside of the electronics housing. Biocompatibility for the hydrogel has been established.	Two electrode integrated within the device. The hydrogel is in 3 discrete sections covering each of the electrodes and the anterior section of strap. Biocompatibility for the hydrogel has been established.	Design of firefly T-2 has been improved to prevent leakage current between the two electrodes through the hydrogel.
Cables/ connectors	Integrated device: no separate cables	Integrated device: no separate cables	Same
User Contact	Contact is made through integrated self-adhesive electrodes. The firefly T-1 is a single channel device.	Contact is made through integrated self-adhesive electrodes. The firefly T-2 is a single channel device.	Same

Discussion of differences

The firefly™ T-2 device has been redesigned from the original firefly™ T-1 device for more efficient current delivery, enabling shorter pulse widths at each stimulus level. Because the T-1 device had a single piece of hydrogel covering both electrodes: there was a small amount of leakage current between the electrodes. The leakage current could reduce the effectiveness of stimulation in users with high skin resistance. The T-2 device was redesigned using discrete pieces of hydrogel over each electrodes to prevent any current leakage. To compensate for the result that more current is available to the uiser, the pulse widths have been reduced to ensure that the same charge is delivered for each pulse width setting.

The firefly™ T-2 interface has been designed to improve ease of use. Using + and – buttons to increase and decrease intensity is somewhat easier than using different length presses on a single button. The two LED indicators used with the T-2 make it easier to see whether the device is operating. One LED for the T-2 device flashes rapidly when the switch is operated by a button press, providing the operator with visual feedback that the button has been operated. The other LED indicates the stimulation level in the same manner as for the T-1.

The changes resulting in the firefly™ T-2 device do not alter the device intended use, indications for use or fundamental scientific technology, and none of the changes significantly affect the safety or effectiveness of the device.

H. Testing to Validate Changes

The device changes described in this Special 510(k) were implemented under the company's design change procedures. A risk assessment of the changes resulted in the following verification and validation activities:

Electrical Safety and Electromagnetic Compatibility Testing – The firefly™ T-2 has been certified to comply with the applicable clauses of the following standards:

- IEC 60601-1:2005 + A1:2012: Medical Electrical Equipment - Part 1: General Requirements for Safety (FDA recognition #19-40
- IEC 60601-2-10:2016 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (FDA recognition #17-16)
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (FDA recognition #19-8)

Hardware/Firmware Testing

As with the predicate device, the firefly™ T-2 hardware and firmware work together and need to be tested together in order to verify the correct functioning of the device. Testing included the following:

- Verification of output waveform characteristics via oscilloscope output tracings at 500Ω, 2kΩ and 10kΩ
- Measurements to compare the firefly™ T-2 output currents to those of the firefly™ T-1 under loads ranging from 500Ω to 10kΩ
- Validation of all firefly™ T-2 hardware and firmware functionality

All test results demonstrated that the firefly™ T-2 meets the predefined device technical and functional requirements specifications.

I. Conclusions

The information and testing presented in this 510(k) demonstrate that that the firefly™ T-2 performs as designed and intended and is substantially equivalent to the predicate device, the firefly™ T-1.