MAY 15 2014

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:

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B. Date Prepared: May 9, 2014

C. Device Name and Classification Information:

Trade Name:	firefly™ T-1
Common Name:	Powered Muscle Stimulator for Muscle Conditioning
Classification:	21 CFR 890.5850, Class II
Product Code:	NGX
Panel:	89, Physical Medicine

D. Predicate Device: Compex® Sport Plus (K083140)

E. Device Description:

The firefly™ T-1 device is a disposable, fully integrated neuromuscular stimulator for muscle conditioning 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 which provides a means of attachment of the device and electrical contact with the patient. A single button controls the On/Off function and the intensity level of the device, which is achieved through changes in the delivered pulse width. The firefly™ T-1 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 firefly™ T-1 stimulus intensity varies with the pulse width, which can be set to one of seven levels to produce the appropriate muscle contraction within the user comfort zone (70µs, 100µs, 140µs, 200µs, 280µs, 400µs, and 560µs). The asymmetric biphasic waveform results in a net charge of zero to the user 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 user through a hydrogel layer applied during manufacture to the integrated electrode. The firefly™ T-1 skin contacting materials have been 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.

An optional firefly™ T-1 strap can be purchased separately and secured over the firefly™ T-1 to assure good electrode contact even for active users. The strap is made of soft neoprene sponge with a nylon cover.

F. Indications for Use:

The firefly™ T-1 device is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The firefly™ T-1 device is not intended to be used in conjunction with therapy or treatment diseases of medical or medical conditions of any kind.

G. Contraindications

This device should not be used by anyone with a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

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

Parameter	firefly™ T-1	Compex® Sport Plus (K083140)	Substantial Equivalence
Intended Use and Indications for Use	Intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The firefly™ T-1 device is not intended to be used in conjunction with therapy or treatment diseases of medical or medical conditions of any kind.	Intended to stimulate healthy muscles in order to improve or facilitate muscle performance. Compex® Sport is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Compex® Sport training programs are designed for injured or ailing muscles and its use on such muscles is contraindicated.	Same
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. Both devices are for OTC use by athletes.
Anatomical Sites	The firefly™ T-1 with the embedded electrodes is applied to the posterior aspect of the knee only for stimulation of the peroneal nerve.	Electrodes can be applied to multiple anatomical sites, including the posterior aspect of the knee only for stimulation of the peroneal nerve.	Substantially equivalent. Both devices can be used for stimulation of the peroneal nerve.
Stimulator Parameters			
Power source	One CR2032 primary lithium coin cell. Not replaceable by user	Battery NIMH, rechargeable	Substantially equivalent. Both devices are battery powered.
-Method of Line Current Isolation	N/A	N/A	
-Patient Leakage Current -Normal	< 20 µA	Unknown	Unable to compare. Leakage current of firefly™ T-1 is

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Condition -Single Fault Condition	< 20 µA	Unknown	extremely low and meets safety standards.
Avg DC current through electrodes when device is on but no pulses are being applied	0 µA	Unknown	Substantially equivalent or better
Number of output modes	Single mode with seven discrete stimulation settings corresponding to the seven pulse widths.	Nine output modes	Substantially equivalent to "Active Recovery" and "Recovery Plus" modes of predicate.
Number of output channels / synchronous or alternating?	Single channel N/A	Four channels Synchronous with 2 msec delay between channels	Substantially equivalent. Firefly™ T-1 only needs one channel for the single operating mode.
-Method of channel isolation	N/A (single channel)	Unknown	Substantially equivalent. No channel isolation needed for firefly™ T-1.
Regulated current or regulated voltage	Current	Unknown	Substantially equivalent. Firefly™ T-1 complies with applicable electrical safety standards.
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

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Indicator display:			
- On/Off status	Yes	Yes	Same
- Low battery	Yes (device switches off)	Yes	Same
-Voltage / current level	N/A (device has fixed constant current). Stimulus level is indicated by flashing LED.	Yes	Substantially equivalent. Both devices provide visible indication of stimulus level.
Timer range in minutes	1800 minutes maximum (device is disabled after 30 hours battery run time)	Active Recovery mode: 23 minute cycle Recovery Plus mode: 25 minute cycle Both can be reset	Substantially equivalent. Both devices can be used for extended periods.
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	Yes IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2	Substantially equivalent
Compliance with 21 CFR 898	N/A (electrodes are integral with the device, there are no separate leads)	Unknown	Not applicable to firefly™ T-1
Weight	0.64 oz (18 g)	12.5 oz (350 g)	Substantially equivalent. Both devices are small and lightweight.
Dimensions	6" x 1.6" x 0.43"	5.6" x 1.5" x 3.9"	Substantially equivalent
Housing material and construction	Plastic injection molding	Plastic injection molding	Substantially equivalent

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Waveform Parameters			
Waveform **- Pulsed monophasic or biphasic** **- Shape**	Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	Biphasic Rectangular	Same Same
Maximum output voltage (± 15%)	13.5 V @ 500 Ω 54 V @ 2 kΩ 110 V @ 10 k Ω	58 V @ 500 Ω 136 V @ 2 kΩ 137 V @ 10 k Ω	Firefly™ T-1 operates at lower voltages. Performance testing demonstrates safe and effective stimulation to facilitate muscle recovery.
Maximum output current (± 15%)	27 mA @ 500 Ω 27 mA @ 2 kΩ 11 mA @ 10 kΩ	120 mA @ 500 Ω 68 mA @ 2 kΩ 13.7 mA @ 10 kΩ	Firefly™ T-1 operates at lower currents. Performance testing demonstrates safe and effective stimulation to facilitate muscle recovery.
Pulse widths	70, 100, 140, 200, 280, 400, 560 µs	400 µs total (200 µs per phase)	Firefly™ T-1 offers a wider range of pulse widths. Users can choose the stimulus level needed for muscle twitch.
Frequency	1 Hz	Active Recovery: frequency cycles in preset pattern between 1 Hz and 9 Hz Recovery Plus: frequency cycles in preset pattern between 1 Hz and 6 Hz	Firefly™ T-1 pulse is fixed at 1 Hz while predicate programs run through the range of low frequencies shown. Performance testing of firefly™ T-1 demonstrates safe and effective stimulation to facilitate muscle recovery.

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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.	Yes 200 µs for positive phase 200 µs for negative phase	Both devices have zero net charge to patient. Performance testing of firefly™ T-1 demonstrates safe and effective stimulation to facilitate muscle recovery.
Net charge **-How achieved**	0 µC at 500 Ω Capacitor coupling	0 µC at 500 Ω Unknown	Same Both devices have zero net charge.
Maximum phase charge (@500Ω)	18.3 µC	96 µC	Lower phase charge for firefly™ T-1
Maximum rms current density (@500Ω)	0.169 mA/cm^2 rms	Active Recovery: 0.29 mA/cm^2 rms Recovery Plus: 0.24 mA/cm^2 rms	Lower current density for firefly™ T-1
Maximum avg current (average absolute value) (@500Ω)	0.037 mA	Active Recovery: 0.43 mA Recovery Plus: 0.29 mA	Lower max average current for firefly™ T-1
Maximum avg power density (using smallest electrodes) (@500Ω)	0.000044 W/cm^2	Active Recovery: 0.00104 W/cm^2 Recovery Plus: 0.00069 W/cm^2	Lower power density for firefly™ T-1
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 (single pulse delivered at 1 Hz continuously while device is powered on)	N/A (selected program delivered continuously while device is powered on)	Same

Parameter	firefly™ T-1	Compex® Sport Plus (K083140)	Substantial Equivalence
Electrodes	Integrated within the device. Hydrogel applied to silver electrode. Biocompatibility for the hydrogel has been established.	Provided with four large and four small self-adhesive electrodes	Substantially equivalent. Both comply with FDA recognized standards.
Cables/ connectors	Integrated device: no separate cables	Separate electrode cables, color coded for the four channels: channel 1 = blue channel 2 = green channel 3 = yellow channel 4 = red	Separate cables not needed for firefly™ T-1

I. Nonclinical Data:

The following nonclinical testing was provided in this 510(k):

Shelf Life Testing – Real-time shelf life testing was conducted. Devices in their final packaging were stored under controlled conditions at 30°C for 27 months then subjected to full technical performance testing following 24 hours of operation. The results of this testing confirmed that the device remains fully operational in accordance with its performance specifications after 27 months of aging, and support a labelled shelf life of 24 months.

Biocompatibility Testing – The skin contacting material of the firefly™ T-1 device (hydrogel) was subjected to biocompatibility testing per ISO 10993-1:2009, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing," for devices in contact with intact skin, including cytotoxicity, dermal sensitization, and dermal irritation. In view of the potential for repeated sequential use of the device, repeat dermal irritation testing was also conducted. All tests passed.

Software Verification and Validation – Software documentation consistent with a moderate level of concern was submitted in this 510(k). Latent software design flaws or faults would not be expected to result in serious user

or patient injury. System validation testing presented in this 510(k) demonstrated that all software requirement specifications were met and all software hazards were mitigated to risk level 1 (Accept).

Electrical Safety and Electromagnetic Compatibility Testing – The firefly™ T-1 device has been certified by Intertek to comply with the applicable clauses of the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; +A1:1991-11, +A2, 1995
- IEC 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators; 1987; +A1 2001
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 3rd edition, 2007.

Engineering Bench Testing – In addition to the full system validation testing, the 510(k) also included testing in accordance with the recommendations of FDA's Guidance Document for Powered Muscle Stimulator 510(k)s, Attachment II, Section 1 – Output Waveforms. Oscilloscope tracings were obtained of the device output waveforms at each pulse width (i.e., intensity settings 1 through 7) under loads of 500Ω, 2 kΩ and 10kΩ. These tracings demonstrated that the net charge in the firefly™ T-1 output waveform at all settings is 0.

J. Clinical Data

The safety and effectiveness of the firefly™ T-1 has been evaluated in independent clinical studies. The early work of Tucker et al.[1] established that a 1 Hz frequency electrical stimulus, applied at the common peroneal nerve, resulted in significant increases ($p<0.01$) in venous volume flow, blood flow velocity, and microcirculatory flux in the stimulated leg as compared to the non-stimulated control leg. The changes in blood flow parameters were comparable amongst all stimulus frequencies (1 Hz to 5Hz); however, the highest amplitude/frequency programs reached a moderate discomfort level

[1] Tucker AT, Maass A, Bain DS, Chen L, Azzam M, Dawson H, Johnston A. Augmentation of venous, arterial and microvascular blood supply in the leg by isometric neuromuscular stimulation via the peroneal nerve. *Int J Angiol* 2010; Spring 19(1): e31-7.

on the subject verbal rating scale, while the lowest frequency of 1 Hz was well tolerated by all subjects. This work formed the basis for developing the firefly™ T-1 device.

Subsequently, two independent investigators studied the safety and efficacy of the device technology (also implemented in the geko™ T-1) for increasing blood flow. Warwick et al.[2] and Jawad et al.[3] both applied the device to the common peroneal nerve of healthy volunteers, setting the simulation level to elicit a palpable twitch of the foot, according to the manufacturer's instructions. In the first study, blood flow measurements were obtained with the subjects in four positions: 1) lying supine, lower limb horizontal; 2) supine, lower limb elevated at 25 to 35 degrees hip flexion; 3) standing, non weight-bearing (weight on contralateral leg only); and 4) standing, weight-bearing (weight evenly distributed on both legs) both with and without a plaster cast applied. In the second study, the impact on blood flow from electrical stimulation was compared to that from intermittent pneumatic compression (IPC) devices. Both studies demonstrated significant increases in blood flow when using the firefly™T-1 electrostimulation device with no safety concerns.

A clinical study of the firefly™ T-1 conducted by Ferguson et al.[4], examined the effects of the electrical stimulation alone compared to graduated compression socks alone or passive recovery (no intervention) on muscle soreness, strength, and markers of muscle damage and inflammation following intense intermittent exercise in 21 healthy males. The study results demonstrated that athletes using the firefly™ T-1 had significantly lower scores for perceived muscle soreness at 24 and 48 hours post exercise as compared to the groups using graduated compression socks or passive recovery.

[2] Warwick D, Shaikh A, Gadola S, Stokes M, Worsley P, Bain D, Tucker A, Gadola SD: Neuromuscular electrostimulation via the common peroneal nerve promotes lower limb flow in a below-knee cast: a potential thromboprophylaxis. *Bone Joint Res*, Sep 2013, 2(9):179-85.
[3] Jawad H, Bain DS, Dawson H, Crawford K. A comparative study investigating the effectiveness of neuromuscular electrostimulation versus intermittent pneumatic compression in enhancing lower limb blood flow in healthy subjects. Submitted for publication to *J Thrombosis and Haemostasis.*
[4] Ferguson R, Dodd M, Paley V: Neuromuscular electrical stimulation via the peroneal nerve reduces muscle soreness following intermittent exercise. Submitted for publication to *Eur J Applied Physiol.*

I. Conclusions

The information and testing presented in this 510(k) demonstrates that the firefly™ T-1 device performs as designed and intended and is substantially equivalent for use as a neuromuscular stimulator for muscle conditioning.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

Firstkind Ltd
c/o Sheila Hemeon-Heyer
Radcliffe Consulting, Inc.
231 Fairbanks Street
West Boylston, MA 01583

Re: K134001
Trade/Device Name: firefly T-1
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: April 17, 2014
Received: April 18, 2014

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K134001

Device Name
firefly™ T-1

Indications for Use *(Describe)*
The firefly™ T-1 device is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The firefly™ T-1 device is not intended to be used in conjunction with therapy or treatment diseases of medical 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.05.15 16:09:31 -04'00'

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