



Food and Drug Administration
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October 23, 2015

Firstkind Limited
c/o Sheila Hemeon-Heyer
President
Heyer Regulatory Solutions, LLC
125 Cherry Lane
Amherst, MA 01002

Re: K152677
Trade/Device Name: geko™ T-2 Neuromuscular Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: September 18, 2015
Received: September 24, 2015

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152677

Device Name
geko T-2 Neuromuscular Stimulator

Indications for Use (Describe)

The geko T-2 Neuromuscular Stimulator is intended for:

- Increasing local blood circulation; and
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis.

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) 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
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Contact: Rachel Fallon, Chief Technology Officer
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Email: rachel.fallon@firstkindmedical.com

B. Date Prepared: September 18, 2015

C. Device Name and Classification Information:

Trade Name: geko™ T-2 Neuromuscular Stimulator
Common/usual Name: Powered Muscle Stimulator
Classification Name: Stimulator, Muscle, Powered
Product Code, CFR: IPF, 21 CFR 890.5850
Panel code: 89
Class: II

D. Predicate Device: K133638, geko™ T-1 Neuromuscular Stimulator

E. Device Description:

The geko™ T-2 Neuromuscular Stimulator (geko™ 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 which 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 geko™ 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 geko™ 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 geko™ T-2 is intended for:

- Increasing local blood circulation, and
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis.

G. Contraindications

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

Powered muscle stimulators should not be used on patients with recently diagnosed deep vein thrombosis.

H. Substantial Equivalence

Parameter	Predicate geko™ T-1	Proposed geko™ T-2
Intended Use and Indications for Use	<ul style="list-style-type: none"> Increasing local blood circulation Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis 	Same
Clinical application	Prescription use only for use in a clinical or home use setting. Single patient use for up to 30 hours Disposable (cannot be reused)	Same
Anatomical Sites	The electrodes are applied to the posterior aspect of the knee only for stimulation of the peroneal nerve.	Same
Shelf Life	24 months	Same
Power source	One CR2032 primary lithium coin cell. Not replaceable by user	Same
-Method of Line Current Isolation	N/A	N/A
-Patient Leakage Current		
-Normal Condition	< 20µA	Same
-Single Fault Condition	< 20µA	Same
# output modes	Single mode with seven discrete stimulation settings corresponding to the seven pulse widths.	Same
# output channels	Single channel	Same
-Synchronous or alternating	N/A (single channel)	Same
-Method of channel isolation	Capacitor	Same

Parameter	Predicate geko™ T-1	Proposed geko™ T-2
Regulated current or regulated voltage	Current regulated	Same
Microprocessor controlled?	Yes	Same
Automatic overload trip	Yes	Same
Automatic no-load trip	Yes	Same
Automatic shut-off	Yes	Same
Patient over-ride control	Yes	Same
Indicator display		
- On/Off status	Yes	Same
- Low battery	Yes (automatic off)	Same
-Voltage / current level	N/A (fixed constant current) Yes, number of LED flashes indicate stimulation level	Same
-Charge level (pulse width)		Same
Timer range in minutes	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	Yes IEC 60601-1:2005, 3 rd ed IEC 60601-2-10:2012, 2 nd ed EN 60601-1-2:2007, 3 rd ed ISO 10993-1
Compliance with 21 CFR 898	N/A (electrodes are integral with the device, there are no separate leads)	Same
Weight	18 g	10 g
Dimensions	6" x 1.6" x 0.43"	7.8" x 1.2" x 0.4"
Housing material and construction	Plastic injection molding	Same
Waveform	Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	Same

Parameter	Predicate geko™ T-1	Proposed geko™ T-2
Maximum output voltage	13.5 V @ 500 Ω 54 V @ 2000 Ω 110 V @ 10,000 Ω	14.0 V @ 500 Ω 53.5 V @ 2000 Ω 255 V @ 10,000 Ω
Maximum output current	27 mA @ 500 Ω 27 mA @2000 Ω 11 mA @ 10,000 Ω	27.9 mA @ 500 Ω 26.8 mA @2000 Ω 25.5 mA @ 10,000 Ω
Pulse width	70, 100, 140, 200, 280, 400, 560 μs	40, 70, 100, 140, 200, 280, 400 μs
Frequency	1 Hz	Same
For interferential modes only: -beat Frequency (Hz)	N/A	Same
Multiphasic waveforms		
-Symmetrical phases	No	Same
-Phase duration	70-560 μs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant	50-400 μs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant
Net charge	0 μC at 500 Ω	Same
-How achieved	Capacitor coupling	Same
Maximum phase charge	18.3 μC at 500 Ω	Same
Maximum current density	6.67 mA/cm ²	Same
Maximum power density	0.000044 W/cm ²	Same
Burst mode a) Pulses per burst b) Bursts per second c) Burst duration (seconds) d) Duty Cycle [Line (b) x Line (c)]	N/A (single pulse, no pulse train or burst)	Same
ON Time (seconds) OFF Time (seconds)	N/A Stimulation is delivered at 1 Hz, with single pulses of 70μs to 560μs	N/A Stimulation is delivered at 1 Hz, with single pulses of 50μs to 400μs

Parameter	Predicate geko™ T-1	Proposed geko™ T-2
Electrodes	Hydrogel applied to silver electrode. Biocompatibility for the hydrogel has been established.	Same
Cables/ connectors	Integrated device: no separate cables	Same
Patient-contact	Contact is made through integrated self-adhesive electrodes. The geko™ T-1 is a single channel device.	Same

Discussion of differences

The geko™ device has been redesigned for more efficient current delivery, enabling shorter pulse widths at each stimulus level. Replacing the one button design of the geko™ T-1 with a two button design in the geko™ T-2 improves ease of use. The changes resulting in the geko™ 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.

I. Nonclinical Data:

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 geko™ T-2 has been certified to comply with the applicable clauses of the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Safety, 3rd edition, 2005
- IEC 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators, 2nd edition,
- 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.

Hardware/Firmware Testing

As with the predicate device, the geko™ 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 geko™ T-2 output currents to those of the geko™ T-1 under loads ranging from 500Ω to 10kΩ
- Validation of all geko™ T-2 hardware and firmware functionality
- Usability evaluations by healthy volunteers
- Clinical evaluations of the ability to achieve adequate stimulation (calf and foot twitches) in patients immediately post-operative following elective total hip replacement at a hospital in the United Kingdom

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

I. Conclusions

The information and testing presented in this 510(k) demonstrated that that the geko™ T-2 performs as designed and intended and is substantially equivalent to the predicate device, the geko™ T-1, for increasing local circulation and immediate post-surgical prevention of venous thrombosis.