



Food and Drug Administration  
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April 8, 2016

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

Re: K160299  
Trade/Device Name: Geko™ Plus R-2 Neuromuscular Stimulator  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered Muscle Stimulator  
Regulatory Class: Class II  
Product Code: IPF  
Dated: March 10, 2016  
Received: March 11, 2016

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. 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" (21 CFR 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,

**Carlos L. Peña -S**

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)

K160299

Device Name

geko(TM) Plus R-2 Neuromuscular Stimulator

Indications for Use (Describe)

The geko(TM) Plus R-2 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.

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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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**B. Date Prepared:** April 8, 2016

**C. Device Name and Classification Information:**

Trade Name: geko™ Plus R-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:** K152677, geko™ T-2 Neuromuscular Stimulator

**E. Device Description:**

The geko™ Plus R-2 Neuromuscular Stimulator (geko™ Plus R-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™ Plus R-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 eight levels for the geko™ Plus R-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™ Plus R-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-2	Proposed geko™ Plus R-2
<b>Intended Use and Indications for Use</b>	<ul style="list-style-type: none"> <li>• Increasing local blood circulation</li> <li>• Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis</li> </ul>	Same
<b>Clinical application</b>	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
<b>Anatomical Sites</b>	The electrodes are applied to the posterior aspect of the knee only for stimulation of the peroneal nerve.	Same
<b>Shelf Life</b>	24 months	Same
<b>Power source</b>	One CR2032 primary lithium coin cell. Not replaceable by user	Same
<b>-Method of Line Current Isolation</b>	N/A	N/A
<b>-Patient Leakage Current</b> <b>-Normal Condition</b> <b>-Single Fault Condition</b>	 < 20µA  < 20µA	 Same  Same
<b># output modes</b>	Single mode with 7 discrete stimulation settings corresponding to the 7 pulse widths.	Single mode with 8 discrete stimulation settings corresponding to the 8 pulse widths.
<b># output channels</b>	Single channel	Same
<b>-Synchronous or alternating</b>	N/A (single channel)	Same
<b>-Method of channel isolation</b>	Capacitor	Same

Parameter	Predicate geko™ T-2	Proposed geko™ Plus R-2
<b>Regulated current or regulated voltage</b>	Current regulated	Same
<b>Microprocessor controlled?</b>	Yes	Same
<b>Automatic overload trip</b>	Yes	Same
<b>Automatic no-load trip</b>	Yes	Same
<b>Automatic shut-off</b>	Yes	Same
<b>Patient over-ride control</b>	Yes	Same
<b>Indicator display</b>		
- 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
<b>Timer range in minutes</b>	1800 minutes maximum (device is disabled after 30 hours battery run time)	Same
<b>Compliance with voluntary standards</b>	Yes IEC 60601-1:2005, 3 <sup>rd</sup> ed IEC 60601-2-10:2012, 2 <sup>nd</sup> ed EN 60601-1-2:2007, 3 <sup>rd</sup> ed ISO 10993-1	Yes Same
<b>Compliance with 21 CFR 898</b>	N/A (electrodes are integral with the device, there are no separate leads)	Same
<b>Weight</b>	10 g	Same
<b>Dimensions</b>	7.8" x 1.2" x 0.4"	Same
<b>Housing material and construction</b>	Plastic injection molding	Same
<b>Waveform</b>	Biphasic (asymmetrical biphasic with zero net DC) Rectangular, with charge balancing second phase	Same

Parameter	Predicate geko™ T-2	Proposed geko™ Plus R-2
<b>Maximum output voltage</b>	13.5 V @ 500 Ω 54 V @ 2000 Ω 255 V @ 10,000 Ω	27 V @ 500 Ω 108 V @ 2000 Ω 255 V @ 10,000 Ω
<b>Maximum output current</b>	27 mA @ 500 Ω 27 mA @2000 Ω 25.5 mA @ 10,000 Ω	54 mA @ 500 Ω 54 mA @2000 Ω 25.5 mA @ 10,000 Ω
<b>Pulse width</b>	50, 70, 100, 140, 200, 280, 400 μs	50, 70, 100, 140, 200, 280, 400, 560 μs
<b>Frequency</b>	1 Hz	Same
<b>For interferential modes only: -beat Frequency (Hz)</b>	N/A	Same
<b>Multiphasic waveforms -Symmetrical phases</b>	No	Same
<b>-Phase duration</b>	50-400 μs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant	50-560 μs for positive phase, second (negative) phase is an exponential decay with a 0.1 s time constant
<b>Net charge</b>	0 μC at 500 Ω	Same
<b>-How achieved</b>	Capacitor coupling	Same
<b>Maximum phase charge*</b>	10.8 μC at 500 Ω	30.2 μC at 500 Ω
<b>Maximum current density*</b>	5.5 mA/cm <sup>2</sup>	11.0 mA/cm <sup>2</sup>
<b>Average (r.m.s.) current density*</b>	0.11 mA/cm <sup>2</sup>	0.26 mA/cm <sup>2</sup>
<b>Maximum power density (averaged over the duty cycle)*</b>	0.000000012 W/cm <sup>2</sup>	0.000000093 W/cm <sup>2</sup>
<b>Burst mode a) Pulses per burst b) Bursts per second c) Burst duration (seconds) d) Duty Cycle [Line (b) x Line (c)]</b>	N/A (single pulse, no pulse train or burst)	Same

Parameter	Predicate geko™ T-2	Proposed geko™ Plus R-2
<b>ON Time (seconds)</b> <b>OFF Time (seconds)</b>	N/A Stimulation is delivered at 1 Hz, with single pulses of 50µs to 400µs	N/A Stimulation is delivered at 1 Hz, with single pulses of 50µs to 560µs
<b>Electrodes</b>	Hydrogel applied to silver electrode. Biocompatibility for the hydrogel has been established.	Same
<b>Cables/ connectors</b>	Integrated device: no separate cables	Same
<b>Patient-contact</b>	Contact is made through integrated self-adhesive electrodes.	Same

\*Values are calculated using the device design specifications (i.e., nominal values).

Discussion of differences

The primary change from the predicate geko™ T-2 to the new geko™ Plus R-2 is that the new device model provides options for stronger stimulation to enable treatment for patients who do not achieve sufficient stimulation with the geko T-2. The stronger stimulation is achieved primarily by the higher constant current (54 mA vs 27 mA) along with a higher maximum pulse width setting (560 µs vs 400 µs). There are no changes to the indications for use, fundamental scientific principles, or operation of the device.

The higher current and pulse width settings do not raise new questions of safety or effectiveness. The maximum voltage is the same for both the new and predicate devices (255 V). The maximum current of the new device, although twice that of the predicate, is still low for a powered muscle stimulator, delivering an average (r.m.s) current density of 0.26 mA/cm<sup>2</sup>, well below the 2 mA/cm<sup>2</sup> maximum limit as set by IEC 60601-2-10:2012 (Medical electrical equipment: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators) and a maximum power density (averaged over the duty cycle) of 0.000000093 W/cm<sup>2</sup>, well below the maximum limit of 0.25 W/cm<sup>2</sup> stated in FDA's Guidance Document for Powered Muscle Stimulator 510(k)s. The longer pulse width of 560 µs for the new device is the same as the longest pulse width for the original geko™ T-1 device cleared under K133638, which served as the predicate device for the geko™ T-2.

## I. Design Validation Activities

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™ Plus R-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, 3<sup>rd</sup> edition, 2005
- IEC 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators, 2<sup>nd</sup> 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, 3<sup>rd</sup> edition, 2007.

### Hardware/Firmware Testing

As with the predicate device, the geko™ Plus R-2 hardware and firmware were 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
- Validation of all geko™ Plus R-2 hardware and firmware functionality

All test results demonstrated that the geko™ Plus R-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™ Plus R-2 performs as designed and intended and is substantially equivalent to the predicate device, the geko™ T-2, for increasing local circulation and immediate post-surgical prevention of venous thrombosis.