May 23, 2018

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

Re: K181059
Trade/Device Name: geko™ T-3 Neuromuscular Stimulator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 23, 2018
Received: April 23, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

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

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)*
K181059

Device Name

geko™ T-3 Neuromuscular Stimulator

Indications for Use *(Describe)*

- Increasing local blood circulation
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis
- Edema reduction

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 23, 2018

C. Device Name and Classification Information:

Trade Name:	geko™ T-3 Neuromuscular Stimulators
Classification Name:	Stimulator, Muscle, Powered
Product Code, CFR:	IPF, 21 CFR 890.5850
Panel code:	89
Class:	II

D. Predicate Devices: K180082 for geko™ T-2 and geko™ Plus R-2

E. Device Description:

The geko™ T-3 Neuromuscular Stimulator (geko™ T-3) is single-patient use and disposable, with fully integrated electronics composed of a constant current pulse generator with embedded software and a lithium-ion battery enclosed in a 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-3 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 11 levels: 35, 50, 70, 100, 140, 200 or 280 @ 27 mA; 280 or 400 @ 38 mA; and 400 or 560 @ 54 mA. 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 calf and foot muscles with a cadence and energy similar to that of walking.

F. Indications for Use:

- Increasing local blood circulation
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis
- Edema reduction

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

The geko™ T-3 Neuromuscular Stimulator device incorporates the stimulus output levels of the geko™ T-2 and geko™ Plus R-2 into a single device.

Parameter	Predicate geko™ T-2	Predicate geko™ Plus R-2	Proposed geko™ T-3
Indications for use	• Increasing local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Edema reduction	• Increasing local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Edema reduction	• Increasing local blood circulation • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Edema reduction
Number of output modes	1	1	1
Number of output channels - Synchronous or alternating? - Method of channel isolation?	1 N/A N/A	1 N/A N/A	1 N/A N/A
Method of stimulus regulation	Current regulated	Current regulated	Current regulated
Microprocessor controlled?	Yes	Yes	Yes
Automatic overload trip	Yes	Yes	Yes

Parameter	Predicate geko™ T-2	Predicate geko™ Plus R-2	Proposed geko™ T-3
Automatic no-load trip	Yes	Yes	Yes
Automatic shut-off	Yes	Yes	Yes
Patient over-ride control	Yes	Yes	Yes
Indicator displays **- On/Off status** **- Low battery** **- Stimulus level**	 Yes Yes (device switches off) Yes. Stimulation level (pulse width) is indicated by the number of times the LED flashes in sequence, e.g., a single flash for Level 1 (50 µs/27 mA) up to 7 flashes for Level 7 (400 µs/27 mA)	 Yes Yes (device switches off) Yes. Stimulation level (pulse width) is indicated by the number of times the LED flashes in sequence, e.g., a single flash for Level 1 (50 µs/54 mA) up to 8 flashes for Level 8 (560 µs/54 mA).	 Yes Yes (device switches off) Yes. Stimulation level (pulse width) is indicated by the number of times the LED flashes in sequence, e.g., a single flash for Level 1 (35 µs/27 mA) up to 11 flashes for Level 11 (560 µs/54 mA).
Waveform	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase
Maximum output voltage	14.0 V @ 500 Ω 53.5 V @ 2000 Ω 255 V @ 10,000 Ω All voltages (±10%)	27.0 V @ 500 Ω 108 V @ 2000 Ω 255 V @ 10,000 Ω All voltages (±10%)	27.0 V @ 500 Ω 108 V @ 2000 Ω 255 V @ 10,000 Ω All voltages (±10%)
Maximum output current	27 mA @ 500 Ω 27 mA @2000 Ω 25.5 mA @ 10,000 Ω All currents (±15%)	54 mA @ 500 Ω 54 mA @ 2000 Ω 25.5 mA @ 10,000 Ω All currents (±15%)	54 mA @ 500 Ω 54 mA @ 2000 Ω 54 mA @ 10,000 Ω All currents (±15%)
Pulse widths (µs) (@ current setting)	50, 70, 100, 140, 200, 280, 400 (@ 27 mA)	50, 70, 100, 140, 200, 280, 400, 560 (@ 54 mA)	35, 50, 70, 100, 140, 200, 280 (@ 27 mA); 280, 400 (@ 38 mA); 400, 560 (@ 54 mA)
Frequency	1 Hz, fixed	1 Hz, fixed	1 Hz, fixed
Net charge	0 µC at 500Ω, capacitor coupled	0 µC at 500Ω, capacitor coupled	+/- 0.1 µC at 500Ω, phase balancing
Maximum phase charge	18.3 µC at 500 Ω	40 µC at 500 Ω	40 µC at 500 Ω

Parameter	Predicate geko™ T-2	Predicate geko™ Plus R-2	Proposed geko™ T-3
Maximum current density	6.67 mA/cm^2	13.3 mA/cm^2	13.3 mA/cm^2
Maximum power density	0.000044 W/cm^2	0.000088 W/cm^2	0.000088 W/cm^2
Timer range in minutes	1800 min max (30 hr run time)	1800 min max (30 hr run time)	1800 min max (30 hr run time)
Power source	One 3V lithium coin cell	One 3V lithium coin cell	One 3V lithium coin cell
Weight	10 g	10 g	10 g
Dimensions	7.8" x 1.2" x 0.4"	7.8" x 1.2" x 0.4"	7.8" x 1.2" x 0.4"
Patient contacting materials	Hydrogel (KM10T)	Hydrogel (KM10T)	Hydrogel (KM10T)
Housing material	Polypropylene Plastic injection molding	Polypropylene Plastic injection molding	Polypropylene Plastic injection molding

The differences between the proposed geko™ T-3 and the predicate geko models are:

- More stimulus levels are available to the user: 11 in the geko™ T-3 as compared to 7 in the geko™ T-2 and 8 in the geko™ Plus R-2.
- The geko T-3 offers three constant current levels: 27 mA, 38 mA, and 54 mA; however, these are within the ranges available on the predicate models.
- The geko T-3 offers one additional short pulse width (35 µs) that is below the lowest pulse width available on the predicate models.
- The geko™ T-3 uses a different method of charge balancing; however, the net charge to the user remains essentially zero.

Otherwise, as can be seen from the Technical Comparison Table, the indications for use and technical specifications for the geko™ T-3 are the same as for the predicate models. None of the changes are associated with any new risks, nor do they change the risk levels previously identified in the geko risk analysis.

H. 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™ T-3 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 basic safety and essential performance
- IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10:2012 +A1(2016) Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
- EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

Hardware/Firmware Testing - The geko™ T-3 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™ T-3 hardware and firmware functionality

I. Conclusion

The information and testing presented in this 510(k) demonstrated that that the geko™ T-3 is substantially equivalent to the predicate geko devices, models T-2 and ^{Plus} R-2, for the intended uses of increasing local circulation, immediate post-surgical prevention of venous thrombosis, and edema reduction.