February 11, 2018

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

Re: K180082
Trade/Device Name: geko™ T-2 and geko™ Plus R-2 Neuromuscular Stimulators
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: January 10, 2018
Received: January 11, 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)*
K180082

Device Name

geko™ T-2 and geko™ Plus R2 Neuromuscular Stimulators

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.

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

Contact: Neil Buckley
Head of Quality and Regulatory Affairs

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Email: neil.buckley@firstkindmedical.com

B. Date Prepared: February 9, 2018

C. Device Name and Classification Information:

Trade Name:	geko™ T-2 and geko™ Plus R2 Neuromuscular Stimulators
Classification Name:	Stimulator, Muscle, Powered
Product Code, CFR:	IPF, 21 CFR 890.5850
Panel code:	89
Class:	II

D. Predicate Device:

K162987 for FlowAid FA100 SCCD

E. Device Description:

The geko™ T-2 and geko™ Plus R-2 Neuromuscular Stimulator devices were previously described in K152677 and K160299, respectively. There have been no changes to the design, technical specifications, or manufacturing of these devices since previously cleared. The devices are 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 devices are 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 (ranging from 50 µsec to 400 µsec) and one of eight levels for the geko™ Plus R-2 (ranging from 50 µsec to 560 µsec). The constant current output at each pulse width setting is nominally 27 mA for the geko™ T-2 and 54 mA 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 for both devices and is used to isometrically stimulate the leg 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 purpose of this 510(k) is to add the indication for use of edema reduction to the previously cleared geko™ T-2 and geko™ Plus R-2 devices. There have been no changes to the device design, technical specifications, or operating principles. The geko devices are substantially equivalent to the FlowAid FA100 SCCD, which was cleared for use in edema reduction under K162987. The Table 1 below provides a technical comparison of the two geko models to the FA100 SCCD. Both the geko devices and the FlowAid FA100 SCCD are intended to increase blood flow using low frequency electrical stimulation of the lower limb. The main technological difference between the geko devices and the FlowAid FA100 SCCD is that the geko devices use a single electrode and a 1 Hz frequency, while the FA100 SCCD uses four electrodes that stimulate in a sequential pattern with a choice of three low frequencies (4 Hz, 9 Hz or 14 Hz). The availability of clinical data demonstrating that both devices are safe and effective in reducing edema supports the conclusion that these differences do not raise new questions of safety or effectiveness and, therefore, the geko devices can be found substantially equivalent for the indication of edema reduction.

Table 1. Technical Comparison of geko™ T-2 and geko™ Plus R-2 to Predicate Device

Parameter	geko™ T-2	geko™ Plus R-2	Predicate Device: FlowAid FA100 SCCD
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 • Preventing or retarding disuse atrophy • Edema reduction
Number of output modes	Single mode with seven discrete pulse width settings (50-400 µs) which define the stimulation level	Single mode with eight discrete pulse width settings (50-560 µs) which define the stimulation level	Single mode with three frequency settings and user adjusted stimulus level
Number of output channels - Synchronous or alternating? - Method of channel isolation?	1 N/A N/A	1 N/A N/A	4 Sequential stimulation of electrode pairs: Capacitor isolated
Method of stimulus regulation	Current regulated	Current regulated	Current regulated
Microprocessor controlled?	Yes	Yes	Yes
Automatic overload trip	Yes	Yes	Yes
Automatic no-load trip	Yes	Yes	Yes

Parameter	geko™ T-2	geko™ Plus R-2	Predicate Device: FlowAid FA100 SCCD
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 flashing LED. The number of times LED flashes in sequence indicates the level of stimulation, i.e., a single flash for Level 1 (50 µs pulse width) up to seven flashes in sequence for Level 7 (400 µs pulse width).	 Yes Yes (device switches off) Yes. Stimulation level (pulse width) is indicated by the flashing LED. The number of times LED flashes in sequence indicates the level of stimulation, i.e., a single flash for Level 1 (50 µs pulse width) up to eight flashes in sequence for Level 8 (560 µs pulse width).	 Yes Yes Yes – numerical indication of signal intensity (voltage value)
Waveform	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase for 0 net DC	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase for 0 net DC	Symmetrical, bi-phasic, rectangular wave with 0 net DC
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%)	80 V (±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%)	160 mA (±10%)

Parameter	geko™ T-2	geko™ Plus R-2	Predicate Device: FlowAid FA100 SCCD
Pulse width	50, 70, 100, 140, 200, 280, 400 µs	50, 70, 100, 140, 200, 280, 400, 560 µs	Fixed – 500 µsec
Frequency	1 Hz, fixed	1 Hz, fixed	Three setting options: 4 Hz, 9 Hz, or 14
Net charge	0 µC at 500 Ω, capacitor coupled	0 µC at 500 Ω, capacitor coupled	0 µC, phase balancing
Maximum phase charge	18.3 µC at 500 Ω	40 µC at 500 Ω	8 µC
Maximum current density	6.67 mA/cm^2	13.3 mA/cm^2	6.4 mA/cm2
Maximum power density	0.000044 W/cm^2	0.000088 W/cm^2	0.000041 W/cm2
Timer range in minutes	1800 min maximum	1800 min maximum	No timer Device will operate until turned off by user or battery depleted.
Power source	One CR2032 primary lithium coin cell. Not replaceable by user	One CR2032 primary lithium coin cell. Not replaceable by user	Four 1.2VDC GP NiMH battery cells
Weight	10 g	10 g	230 g, including batteries
Dimensions	7.8” x 1.2” x 0.4”	7.8” x 1.2” x 0.4”	2.8” x 5.1” x 1.1”
Patient contacting materials	Hydrogel (KM10T)	Hydrogel (KM10T)	Hydrogel applied to silver electrode.
Housing material	Polypropylene Plastic injection molding	Polypropylene Plastic injection molding	Injection molded plastic

H. Discussion of Performance Data

A clinical study was conducted to demonstrate the safety and effectiveness of the geko devices in the reduction of edema. Twenty-six subjects undergoing total hip replacement surgery were randomized to receive either the geko™ device (n=14) or compression stockings (n=12). The randomized therapy was applied bilaterally immediately following the surgery and worn continuously until hospital discharge except while bathing or for other procedures. The geko™ devices were changed every 24 hours per the instructions for use. Circumference measurements were taken on both the operated and non-operated legs at the ankle, calf and thigh immediately prior to and following surgery and on each day post-surgery until hospital discharge. The circumference measurements were used to determine the total volume of each leg using a conical model. The results demonstrated less edema formation for the subjects treated with the geko™ devices as compared to compression stockings in both the operated and non-operated legs, which reached statistical significance by Day 1 post-op and continued until hospital discharge. No device-related adverse events or serious adverse events were reported for either the geko™ devices or compression stockings.

I. Conclusion

The clinical data presented in this 510(k) supports the safety and effectiveness of the geko™ devices when used for edema reduction. Therefore, this 510(k) is substantially equivalent for the new indication for use.