September 18, 2019

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

Re: K191113
Trade/Device Name: geko™ T-2 and geko™ T-3 Neuromuscular Stimulators
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 23, 2019
Received: April 26, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Amber T. Ballard -S

For Vivek Pinto, Ph.D.
Director (Acting)
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K191113

Device Name
geko T-2 and geko T-3 Neuromuscular Stimulators

Indications for Use *(Describe)*

- Increasing local blood circulation
- Edema reduction
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis
- Stimulation of the calf muscles to prevent venous thrombosis in non-surgical patients at risk for venous thromboembolism

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
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HP13 7DL

Contact: Neil Buckley
Head of Quality and Regulatory Affairs
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Email: neil.buckley@firstkindmedical.com

B. Date Prepared: September 18, 2019

C. Device Name and Classification Information:

Trade Name:	geko™ T-2 and 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
K181059 for geko™ T-3

E. Device Description:

The geko™ T-2 and geko™ T-3 are single patient use, disposable (after 24 hours), fully integrated neuromuscular stimulator devices. Each model is 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 a follows depending on the device model:

- geko™ T-2: 7 levels ranging from 50 µsec to 400 µsec @ 27 mA
- geko™ T-3: 11 levels ranging from 35 to 280 µsec @ 27 mA, 280 to 400 µsec @ 38 mA, and 400 to 560 µsec at 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 for all device models and is used to isometrically stimulate the leg and foot muscles with a cadence and energy similar to that of walking.

Both device models have the same principles of operation and the same indications for use. The choice of device model depends on the level of stimulation needed to achieve a visible contraction (twitch) of the patient's calf and dorsiflexion of the foot.

F. Indications for Use:

- Increasing local blood circulation
- Edema reduction
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis
- Stimulation of the calf muscles to prevent venous thrombosis in non-surgical patients at risk for venous thromboembolism

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

As shown in the table below, there have been no technological changes to the geko™ device models since they were previously 510(k) cleared. The sole purpose of this 510(k) is to add a new indication for use for prevention of venous thrombosis in non-surgical patients at risk for venous thromboembolism (VTE). The new indication for use is supported by clinical data summarized in Section H.

Parameter	Predicate geko™ T-2	Proposed geko™ T-2	Predicate geko™ T-3	Proposed geko™ T-3
510(k) #	K180082	K191113	K181059	K191113
Indications for Use	• Increasing local blood circulation • Edema reduction • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis	• Increasing local blood circulation • Edema reduction • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Stimulation of the calf muscles to prevent venous thrombosis in non-ambulatory	• Increasing local blood circulation • Edema reduction • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis	• Increasing local blood circulation • Edema reduction • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis • Stimulation of the calf muscles to prevent venous thrombosis in non-ambulatory

Parameter	Predicate geko™ T-2	Proposed geko™ T-2	Predicate geko™ T-3	Proposed geko™ T-3
		patients		patients
Number of output modes	Single mode with 7 discrete pulse width settings which define the stimulation levels	Same	Single mode with 11 discrete pulse width settings which define the stimulation levels	Same
Number of output channels	Single	Same	Single	Same
Method of stimulus regulation	Current regulated	Same	Current regulated	Same
Microprocessor controlled?	Yes	Same	Yes	Same
Automatic overload trip	Yes	Same	Yes	Same
Automatic no-load trip	Yes	Same	Yes	Same
Automatic shut-off	Yes	Same	Yes	Same
Patient over-ride control	Yes	Same	Yes	Same
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)	Same	 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).	Same
Waveform	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase	Same	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase	Same
Maximum output voltage	14.0 V @ 500 Ω 53.5 V @ 2000 Ω 255 V @ 10,000 Ω All voltages (±10%)	Same	27.0 V @ 500 Ω 108 V @ 2000 Ω 255 V @ 10,000 Ω All voltages (±10%)	Same
Maximum output current	27 mA @ 500 Ω 27 mA @2000 Ω 25.5 mA @ 10,000 Ω	Same	54 mA @ 500 Ω 54 mA @ 2000 Ω 54 mA @ 10,000 Ω	Same

Parameter	Predicate geko™ T-2	Proposed geko™ T-2	Predicate geko™ T-3	Proposed geko™ T-3
	All currents (±15%)		All currents (±15%)	
Pulse widths	50, 70, 100, 140, 200, 280, 400 µs	Same	35, 50, 70, 100, 140, 200, 280, 400, 560 µs	Same
Frequency	1 Hz, fixed	Same	1 Hz, fixed	Same
Net charge	0 µC at 500Ω, capacitor coupled	Same	+/- 0.1 µC at 500Ω, phase balancing	Same
Maximum phase charge	18.3 µC at 500 Ω	Same	40 µC at 500 Ω	Same
Maximum current density	6.67 mA/cm^2	Same	13.3 mA/cm^2	Same
Maximum power density	0.000044 W/cm^2	Same	0.000088 W/cm^2	Same
Timer range in minutes	1800 min max (30 hr run time)	Same	1800 min max (30 hr run time)	Same
Power source	One 3V lithium coin cell	Same	One 3V lithium coin cell	Same
Weight	10 g	Same	10 g	Same
Dimensions	7.8” x 1.2” x 0.4”	Same	7.8” x 1.2” x 0.4”	Same
Patient contacting materials	Hydrogel (KM10T)	Same	Hydrogel (KM10T)	Same
Housing material	Polypropylene Plastic injection molding	Same	Polypropylene Plastic injection molding	Same

H. Discussion of Performance Data

A clinical study was conducted to demonstrate the safety and effectiveness of the geko™ in preventing venous thromboembolism (VTE) in a group of patients hospitalized following stroke. The study included all patients admitted to and followed by the Acute Stoke Unit (ASU) at the Royal Stoke University Hospital (RSUH) in Stoke-On-Trent England between November 1, 2016 and March 3, 2018, with a confirmed diagnosis of acute stroke (ischemic or haemorrhagic) or transient ischemic attack (TIA). VTE prophylaxis was prescribed for all stroke patients who were non-ambulatory, defined as not able to walk unaided, and at risk for VTE according to hospital protocol. VTE prophylaxis was by pharmacological means (anticoagulants) unless contraindicated in which case mechanical intermittent pneumatic compression (IPC) was employed. Patients for whom IPC was contraindicated were prescribed the geko™. Patients who began with IPC but became intolerant or non-compliant were allowed to switch to the geko™. Patients who refused VTE prophylaxis were also followed in the study. Patients were assessed for VTE risk within 24 hours of admission, and IPC or geko™, when prescribed, was begun within 3 days of admission for 98.7% (657/666) of the patients. Both IPC and geko™ were applied bi-laterally and used 24

hours/day until hospital discharge. Patients were assessed for incidence of VTE for 90 days following hospital discharge.

A total of 1000 patients were entered into this clinical study. All patients were followed for the 90 day study period. The methods of VTE prophylaxis employed during their period of hospital admission were:

- Pharmacological anti-coagulation (N=125)
- IPC only (N=463)
- geko™ only (N=122)
- IPC & geko™ (started with IPC but switched to geko™ due to non-tolerance or non-compliance with IPC) (N=81)
- Refused VTE prophylaxis treatment (N=22)
- No VTE prophylaxis treatment required (N=187)

The results of this study were that of the 122 patients who received VTE prophylaxis with the geko™ only, none experienced a VTE within the 90-day period of this study. By comparison, 2.4% (11/463) of the patients who received VTE prophylaxis with IPC only, 1.2% (1/81) of patients who started with IPC then switched to geko™, and 4.8% (1/22) of patients who refused VTE prophylaxis experienced a VTE within the 90-day period of this study. Comparison of the results between the geko™ only and IPC only groups demonstrates that the geko™ was non-inferior to IPC within 0.5% (p=0.05) in preventing VTE in this patient population.

In addition, geko™ was shown to be a safe and well-tolerated therapy. While no adverse device-related events (serious or otherwise) were reported for either geko™ or IPC in this study, 81 subjects switched from IPC to geko™ due to non-compliance or dissatisfaction with the IPC.

This was a real-world clinical study. The safety and effectiveness of the devices for prevention of venous thrombosis in non-surgical patients has not been demonstrated in a randomized, controlled clinical study.

I. Conclusion

The clinical data presented in this 510(k) supports the safety and effectiveness of the geko™ devices when used to prevent venous thrombosis in hospitalized patients who are at risk for VTE. Therefore, this 510(k), with the new indication for use, is substantially equivalent to the previously cleared 510(k)s for the geko™ T-2 and geko™ T-3.