DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 10, 2017

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

Re: K163125
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: March 9, 2017
Received: March 10, 2017

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 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,

Michael J. Hoffmann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163125

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

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
K163125

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

A. Submitter:

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High Wycombe, UK
HP13 7DL

Contact: Neil Buckley
Head of Quality and Regulatory Affairs

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B. Date Prepared: April 7, 2017

C. Device Name and Classification Information:

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

D. Predicate Devices: K152677 for geko™ T-2
K160299 for geko™ Plus R-2

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

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. Technical Comparison with the Predicate Device and Discussion of Differences

The purpose of this 510(k) is to modify the device labelling. There have been no design or technical changes to the geko™ T-2 and geko™ Plus R-2 devices since they were originally cleared under K152677 and K160299, respectively.

I. Performance Data

Firstkind submitted data from a simulated use bench test to demonstrate that the geko™ devices are not adversely impacted when used in the presence of high frequency surgical equipment. During the testing, the geko™ device was attached to a gel phantom that simulated the conductive properties of the human limb. A HF electrosurgery device was used to cut into the phantom at various distances from the geko from 500 mm (approximately 20 in) down to 5 mm (approximately 0.2 in) at different speeds, low and high power levels and when used in different

cutting/coagulation modes. The geko™ treatment parameters remained within the stated tolerance values for all of these test cases, confirming no impact to the geko™ operation and no risk of burns to the patient under the tested conditions.

I. Conclusions

The testing presented in this 510(k) supports the removal of the warning in the instructions for use against use of the geko in the presence of high frequency surgical equipment. Therefore, this 510(k) is substantially equivalent to the previously cleared 510(k)s for the geko™ T-2 and geko™ Plus R-2, with the modified labelling.