January 18, 2020

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

Re: K193045
Trade/Device Name: geko™ W-2
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: December 19, 2019
Received: December 19, 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 and Part 809); 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,

For Vivek Pinto, Ph.D.
Director
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)*
K193045

Device Name
geko™ W-2

Indications for Use *(Describe)*
- Increasing local blood circulation
- 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 - K193045

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: November 1, 2019

C. Device Name and Classification Information:

Trade Name:	geko™ W-2
Common Name:	Neuromuscular stimulator
Classification Name:	Stimulator, Muscle, Powered
Product Code, CFR:	IPF, 21 CFR 890.5850
Panel code:	89
Class:	II

D. Predicate Devices: geko™ Plus R-2 as cleared under K180082

E. Device Description:

The geko™ W-2 neuromuscular stimulator is a disposable, fully integrated unit composed of a constant current pulse generator with embedded software, a lithium coin-cell 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 choosing one of 10 stimulus settings.

The geko™ W-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 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. Each geko™

W-2 provides two 6-hour treatments with a 6 hour minimum rest period between treatments. Two optional accessories are available to hold the geko W-2 in place during treatment, if needed: a knee strap and an adhesive tape.

F. Indications for Use:

- Increasing local blood circulation
- Edema reduction

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

Parameter	Proposed geko™ W-2	Predicate geko™ Plus R-2 (K180082)
Indications for use	• Increasing local blood circulation • Edema reduction	• Increasing local blood circulation • Edema reduction • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
# output modes	1	1
# output channels - Synchronous or alternating? - Method of channel isolation?	1 N/A N/A	1 N/A N/A
Method of stimulus regulation	Current regulated	Current regulated
Microprocessor controlled?	Yes	Yes
Automatic overload trip	Yes	Yes
Automatic no-load trip	Yes	Yes
Automatic shut-off	Yes	Yes
Patient over-ride control	Yes	Yes

Parameter	Proposed geko™ W-2	Predicate geko™ Plus R-2 (K180082)
Indicator displays **- On/Off status** **- Low battery** **- Stimulus level**	 Yes 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 (25 µs/54 mA) up to 10 flashes for Level 10 (560 µs/54 mA).	 Yes 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).
Waveform	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase	Asymmetrical, biphasic, rectangular waveform with charge balancing second phase
Maximum output voltage	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	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 25.5 mA @ 10,000 Ω All currents (±15%)
Pulse widths	25, 35, 50, 70, 100, 140, 200, 280, 400, 560 µs	50, 70, 100, 140, 200, 280, 400 and 560µs
Frequency	1 Hz, fixed	1 Hz, fixed
Net charge	0 µC at 500Ω, capacitor coupled	0 µC at 500Ω, capacitor coupled
Maximum phase charge	40 µC at 500 Ω	40 µC at 500 Ω
Maximum current density	13.3 mA/cm^2	13.3 mA/cm^2
Maximum power density	0.000088 W/cm^2	0.000088 W/cm^2
Timer range in minutes	720 minutes max (two 6-hour run times)	1800 minutes max (one 30-hour run time)
Power source	One 3V lithium coin cell	One 3V lithium coin cell
Weight	10 g	10 g
Dimensions	7.8” x 1.2” x 0.4”	7.8” x 1.2” x 0.4”
Patient contacting materials	Hydrogel (KM40A)	Hydrogel (KM10T)

Parameter	Proposed geko™ W-2	Predicate geko™ Plus R-2 (K180082)
Housing material	Polypropylene Plastic injection molding	Polypropylene Plastic injection molding

The differences between the proposed geko™ W-2 and the predicate geko™ Plus R-2 model are:

- More stimulus levels are available to the user: 10 in the geko™ W-2 as compared to 8 in the geko™ Plus R-2. The geko W-2 offers two additional short pulse widths (25 & 35 µs) that are below the lowest pulse width available on the predicate models.
- The geko™ W-2 provides two doses of 6 hours each, with an enforced rest of 6 hours minimum between the doses as compared to the single 30 hour run time for a geko™ Plus R-2.
- The geko™ W-2 uses KM40A instead of KM10T hydrogel.

The reason for these changes is to provide a geko model for patients who only require a lower level or stimulation and/or have sensitive skin. The geko W-2 provides a full range of stimulus intensities including two levels below those currently available for the geko™ Plus R-2. In addition, the KMT40A hydrogel of the geko W-2 has a lower adhesive strength and may be less irritative to sensitive skin than the KMT10T hydrogel used in the other geko models, including the geko Plus R-2. Finally, the 6 hour on/6 hour off treatment protocol gives sensitive skin a chance to rest in between treatment sessions.

Because the geko™ W-2 is limited to 6 hour treatment durations with a minimum of 6 hour rest between treatments, the device is not indicated for prevention of venous thrombosis, which requires continuous (or near continuous) therapy for longer than 6 hours. Therefore, the indications for use of the geko™ W-2 are a subset of those for the prior geko models. Otherwise, as can be seen from the Technical Comparison Table, the indications for use, technical specifications, mechanism of action, and device operation for the geko™ W-2 are the same as for the predicate device.

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:

Biocompatibility testing for the new hydrogel for medical devices in contact with intact skin:

- Cytotoxicity testing according to ISO 10993-5
- Sensitization and Irritation testing according to ISO 10993-10

The testing demonstrated that the KM40A hydrogel is biocompatible for its intended use contact.

Electrical safety testing was not needed as there are no changes in the geko W-2 as compared to the predicate geko™ Plus R-2 related to the electrical hardware.

Electromagnetic compatibility testing was conducted to IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests. Although no electronic hardware changes were made to the geko W-2 as compared to the geko™ Plus R-2, EMC testing was conducted to assure compliance to the current version of the standard. Testing included all requirements for a non-rechargeable, battery powered medical device. Testing was conducted with the device in continuous operating mode at the highest stimulus setting. All tests were passed.

Hardware/Firmware testing – As with the prior geko models, the geko™ W-2 hardware and firmware were tested together in order to verify the correct functioning of the device. All tests were passed. Testing included:

- Verification of output waveform characteristics via oscilloscope output tracings at 500Ω, 2kΩ and 10kΩ
- Validation of all geko™ W-2 hardware and firmware functionality

Performance testing - The durability of the device when used multiple times was verified under internal test protocols that included: 1) assessing the device operation when applied and removed from a test substrate 100 times; and 2) assessing device adhesion when applied and removed for a total of 10 use cycles. All test samples passed all repeat test cases.

I. Conclusion

The information and testing presented in this 510(k) demonstrated that that the geko™ W-2 is substantially equivalent to the predicate geko device models, specifically the geko™ Plus R-2, for the indications for use of increasing local circulation and edema reduction.