November 29, 2021

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

Re: K212762
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: August 31, 2021
Received: August 31, 2021

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 Ballard, PhD
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212762

Device Name

geko W-2

Indications for Use *(Describe)*

The geko W-2 is indicated for:

- Increasing local blood circulation
- Edema reduction
- Increasing microcirculatory blood flow in lower limb soft tissue of patients with venous insufficiency and/or ischemia while the device is active

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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Traditional 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: November 29, 2021

C. Device Name and Classification Information:

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

D. Predicate Device: K193045, geko™ W-2 Neuromuscular Stimulator

E. Device Description:

The geko™ W-2 Neuromuscular Stimulator (geko™ W-2) 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
- Increasing microcirculatory blood flow in lower limb soft tissue of patients with venous insufficiency and/or ischemia while the device is active

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

The purpose of this 510(k) is to add a new indication for use of to the previously cleared geko™ W-2 device. There have been no changes to the device design, technical specifications, or operating principles. The table below demonstrates that the geko W-2 reviewed under this 510(k) is the same as the geko W-2 reviewed under K193045 except for the new indication for use.

Parameter	Predicate geko™ W-2 (K193045)	Proposed geko™ W-2
Indications for use	• Increasing local blood circulation • Edema reduction	• Increasing local blood circulation • Edema reduction • Increasing microcirculatory blood flow in lower limb soft tissue of patients with venous insufficiency and/or ischemia while the device is active
# 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	Yes	Yes

Parameter	Predicate geko™ W-2 (K193045)	Proposed geko™ W-2
control		
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 (25 µs/54 mA) up to 10 flashes for Level 10 (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, and 560 µs	25. 35. 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)	720 minutes max (two 6-hour run times)
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 (KM40A)

Parameter	Predicate geko™ W-2 (K193045)	Proposed geko™ W-2
Housing material	Polypropylene	Polypropylene

There are no differences between the proposed and predicate geko™ W-2 to discuss other than the new indication for use.

H. Discussion of Performance Data

Data from four clinical studies were submitted in this 510(k) to support the safety and effectiveness of the geko™ W-2 device to increase microcirculatory blood flow in the lower limbs of patients with venous insufficiency and/or ischemia. Studies #1 and #2 were acute studies that measured increased microcirculatory blood flow in these patient populations during short-term active geko stimulation as compared to rest. Data from studies #3 and #4 demonstrated the safety of the geko when used daily over multiple weeks by these patient populations and were not used to support the effectiveness of the device. No data were provided to support the safety and effectiveness of the geko W-2 to promote wound healing. The magnitude of the clinical benefit of the geko from increased microcirculatory blood flow in patients with venous insufficiency and/or ischemia remains unclear.

Each of these studies is summarized below.

Study #1: Published in: *Das S, Dhoonmoon L, Chhabra S. Microcirculatory changes in venous leg ulcers using intermittent electrostimulation of common peroneal nerve. Int Wound J 2021 Apr; 18(2):187-93.*

This study was conducted to evaluate the effect of geko stimulation on both arterial and venous microcirculatory blood flow in the lower limb of patients with venous insufficiency and ischemia using Laser Speckle Contrast Imaging (LSCI). Sixteen subjects who were being treated with compression therapy for their VLU at the Ealing Hospital in the United Kingdom participated in this study, including 10 males and 6 females with a mean age of 68 (range 61-79) years and a mean BMI of 27.9 kg/m^2 (range 25.9-29.5 kg/m^2). All microcirculatory blood flow measurements were obtained with the subjects at rest in a seated position. LSCI measurements were obtained for 2 minutes under each of the following conditions: 1) immediately following a 10-minute stabilization period with the geko turned off; and 2) immediately following a 10-minute stabilization period with the geko turned on and actively stimulating the peroneal nerve. The only difference between the two sets of measurements was the geko activation status. Statistically significant increases in both flux and pulsatility were measured when the geko was turned on (active) as compared to the resting state. The results of this study confirmed that use of the geko can increase blood flow in the small vessels (micro-circulation) of the legs in patients with venous insufficiency while the device is active. The measurement of increased blood flow in this study was made during a short (10-minute) period of active device use, and no data were provided by this study to support increased

microcirculatory blood flow during longer device use durations or in the immediate or prolonged reperfusion stages. These data do not support that the geko W-2 has any benefit for wound healing. Adverse events were not reported in this acute study.

Study #2: Published in: *Bosanquet D, Ivins N, Jones N, Harding K. Microcirculatory flux and pulsatility in arterial leg ulcers is increased by intermittent neuromuscular electrostimulation of the common peroneal nerve. Ann Vasc Surg 2021 Feb; 71:308-14.*

This study was conducted to evaluate the effect of geko stimulation on both arterial and venous microcirculatory blood flow in the lower limb of patients with ischemia using Laser Speckle Contrast Imaging (LSCI). Eight subjects who were being treated under the Aneurin Bevan University Health Board and Cardiff and Vale University Health Board in the United Kingdom participated in this study. The subjects included 4 males and 4 females with a mean age of 72 ± 8 years, mean BMI of 25.2 ± 3.1 kg/m2, and mean ABPI of 0.5 ± 0.05. All of the subjects had peripheral artery disease and 50% of the subjects had Type 2 diabetes. All microcirculatory blood flow measurements were obtained with the subjects at rest in a seated position. LSCI measurements were obtained for 2 minutes under each of the following conditions: 1) immediately following a 30-minute stabilization period with the geko turned off; and 2) immediately following a 30-minute stabilization period with the geko turned on and actively stimulating the peroneal nerve. The only difference between the two sets of measurements was the geko activation status. Statistically significant increases in both flux and pulsatility were measured when the geko was turned on (active) as compared to resting state. The results of this study confirm that use of the geko can increase blood flow in the small vessels (microcirculation)of the legs of patients with ischemia while the device is active. The measurement of increased blood flow in this study was made during a short period (30 minutes) while the device was active, and not data were provided by this study to support increased blood flow after period of use longer than 30 minutes or in the immediate or prolonged reperfusion stages. These data do not support that the geko W-2 has any benefit for wound healing. Adverse events were not reported in this acute study.

Study #3: Published in: *Jones N, Ivins N, Ebon V, Hagelstein S, Harding K. Neuromuscular electrostimulation on lower limb wounds. Brit J Nurs 2018; 27(20):516-21.*

This study reported on 25 patients with compromised lower limb circulation being treated at the Welsh Wound Innovation Centre in the UK between September 2015 and January 2017: 17 with venous leg ulcers (VLU), 3 with mixed leg ulcers (MLU), and 3 with diabetic foot ulcers (DFU). This study population included 22 males and 3 females, with a mean age of 69 years (53 to 85 years). All subjects wore the geko in addition to their standard care (i.e., dressing changes, off-loading, and compression, as appropriate) for 6 hours (continuously) per day at home for 8 weeks. Only one adverse event, irritation beneath the electrodes, was reported over the duration of the study. This study demonstrates that patients with compromised lower limb blood flow can safely use the

geko on a prolonged (4 week) daily basis for 6 hours a day. These data do not provide sufficient data to support that the geko W-2 is safe or effective for wound healing.

Study #4: *Interim Report of Ongoing Study – Long-term geko Use by Subjects with Chronic Leg Wounds*

Although this study is not yet completed, Firstkind prepared an interim report of the available study data to provide additional evidence related to the safety of long-term use of the geko W-2 in patients with compromised lower limb circulation. This is an ongoing multi-center study at sites in the UK and EU. As of January 21, 2021, safety data were available for 33 subjects (21 male, 12 female, age ranging from 21-93 years) treated with the geko for either 6 hours per day for 4 weeks (n=15) or 12 hours per day for 4 weeks (n=18). No serious adverse events (SAEs), whether device related or not, were reported for these 33 subjects. A total of 11 device related, non-serious adverse events (AEs) were reported thus far, all of which were mild skin reactions beneath the electrodes: 4 cases in the 15 subjects treated for 6 hours per day (26.7% event rate) and 7 cases in the subjects treated for 12 hours per day (38.9% event rate). None of the skin reactions resulted in a subject being terminated early from the study, although one subject did choose to stop using the device following their completion of the study treatment phase as a result of their rash. These data do not provide sufficient data to support that the geko W-2 is safe or effective for wound healing.

I. Conclusion

The clinical data presented in this 510(k) demonstrate that that the geko™ W-2 is substantially equivalent to the predicate geko™ W-2 device for the indication of increasing microcirculatory blood flow in lower limb soft tissue of patients with venous insufficiency and/or ischemia.