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 6, 2017

DK Electronics, LLC
Avery Huff
Operations Mgr
413-B Elmwood Ave,
Sharon Hill, Pennsylvania 19079

Re: K160323
Trade/Device Name: FlowKeepers®
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH
Dated: February 22, 2017
Received: March 7, 2017

Dear Avery Huff:

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 yours,

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)*
K160323

Device Name
FlowKeepers®

Indications for Use *(Describe)*
Powered Muscle Stimulator
- To temporarily increase local blood circulation in healthy leg muscles
- To stimulate healthy muscles in order to improve and facilitate muscle performance

TENS
- For temporary relief of pain associated with sore and aching muscles of the lower extremities (legs) due to strain from exercise or normal household and work activities

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
K160323

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter:	DK Electronics, LLC
Submitter Address:	413-B Elmwood Ave, Sharon Hill, PA 19079
Phone:	855-494-5158
Facsimile:	484-494-5163
Contact Person:	Avery Huff
Email:	avery_huff@yahoo.com
Date Prepared:	4/6/2017

Trade Name and Classification of Device

Trade Name of Device:	FlowKeepers®
Common Name:	Powered Muscle Stimulator Neuromuscular electrical stimulator devices (NMES)
Classification:	Powered Muscle Stimulator (21 CFR 890.5850)
Product Codes:	Primary - NGX (Stimulator, Muscle, Powered, For Muscle Conditioning) Secondary – NUH (Stimulator, Nerve, Transcutaneous, Over-The-Counter)
Review Panel:	Physical Medicine

Predicate Devices

Revitive IX® (OTC), Actegy Ltd. (K143207) – NGX, NUH 21 CFR 890.5850
Pennypad PP-904 Rapid Relief™ (OTC), HiVox Biotek, Inc. (K140650) – NUH, 21 CFR 890.5890

Intended Use/ Indications for Use

Powered Muscle Stimulator

- To temporarily increase local blood circulation in healthy leg muscles.
- To stimulate healthy muscles in order to improve and facilitate muscle performance.

TENS

- For temporary relief of pain associated with sore and aching muscles in the lower extremities (legs) due to strain from exercise, normal household duties and work activities.

Device Description

The FlowKeepers® is a portable, wearable, battery powered device and delivers electrical stimulation through the skin to the muscles. It provides low frequency (0.1 Hz) muscle stimulation with rectangular, bipolar, biphasic pulses, and operates in a range which balances between comfort and effective contractions. There is a control unit with power buttons and LED flasher. To see how FlowKeepers® technological characteristics are similar to the predicate device, see the comparison chart below under the Substantial Equivalence heading.

Performance Testing

Electromagnetic compatibility, electrical safety testing, and other performance testing were conducted in

accordance with the following standards

IEC 60601-1-8:2006 & A1:2012
Medical electrical equipment Part 1: General requirements for safety

IEC 60601-1-2 Edition 3: 2007-03
Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance
Collateral Standard: Electromagnetic compatibility- Requirements and tests

IEC 60601-1-11 Edition 1.0 2010-04
Medical electrical equipment Part 1-11: General Requirements for basic safety and essential performance
Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-4
Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems

IEC 60601-2-10 Edition 2.0 2012-06
Medical electrical equipment Part 2: Particular requirements for the safety of nerve and muscle stimulators.

In all instances, the FlowKeepers® functioned as intended and the results observed were as expected.

Substantial Equivalence

The FlowKeepers® is substantially equivalent to other powered muscle stimulators such as Revitive IX® OTC (K143207). The FlowKeepers® has the same intended uses and similar indications, technological characteristics, and principles of operation as the Revitive IX® OTC. The difference in design and the minor technological differences between the FlowKeepers® and its predicate device Revitive IX® OTC raise no new issues of safety or effectiveness. Performance data demonstrate that the FlowKeepers® is as safe and effective as the predicate device. Thus, the FlowKeepers® is substantially equivalent.

Comparison of FlowKeepers® with Revitive IX® (OTC) and HiVox Biotek, Inc. Rapid ReliefTM Pennypad PP-904 (OTC)

	DK Electronics, LLC FlowKeepers®	Actegy Ltd. Revitive IX® (OTC)	HiVox Biotek, Inc. Rapid Relief™ Pennypad PP-904 (OTC)
510(k) Number	K160323	K143207	K140650
Product Codes: Model	NGX, NUH FlowKeepers®	NGX, NUH RIX	NUH PP-904
Indications for Use (IFU)	Powered Muscle Stimulator: -Temporarily increase local blood circulation in healthy leg muscles. -To stimulate healthy muscles in order to improve and facilitate muscle performance. TENS -Temporary relief of pain associated with sore and aching muscles in the lower extremities (legs) due to strain from exercise, normal household duties and work activities.	To temporarily increase local blood circulation in healthy leg muscles. To stimulate healthy muscles in order to improve and facilitate muscle performance. For temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties.	The Rapid Relief Pennypad PP-904 is indicated for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg), and lower back due to strain from exercise or normal household and work activities.
Dimensions (mm) [WxHxD]	140.6 mm x 67.14 mm x 10.5 mm	Ø360 mm x 75 mm	113 mm x 70 mm x 9.7 mm
Waveform	Pulsed symmetrical biphasic and bipolar	Pulsed symmetrical biphasic, rectangular and bipolar	Symmetrical biphasic
Shape	Rectangular	Not Available	Rectangular
Power Source(s)	DC 3 V Li Ion battery CR2032	DC 5V	DC 3 V Li Ion battery CR2032
Number of Output Modes	1	1	1
Number of Output Channels	1	2 (1 for Foot, 1 for body pads)	1
Automatic Shut Off	Auto Shut off at 10 hrs, low battery	Automatic Shut off, Override Control	Automatic Shut off at 60 minutes, low battery
Automatic Overload Trip	No	Not Available	No
Automatic No-Load Trip	Yes	Not Available	No
Patient Override Control	Yes	Yes	Yes
Software/Firmware/Microprocessor Control	Yes	Yes	Yes
Weight	0.6 oz (with electrodes) 0.8 oz (with electrodes + battery)	1725 g (not including PSU)	13g (with battery)
Regulated Voltage Level	Yes	Not Available	Yes
Regulated Current Level	No	Not Available	No
Timer Range (minutes)	600 minutes ±10%	1 to 60 min	15 minutes
Indicator Display: On/Off Status Low Battery Voltage/Current Level	LED Power On/Off, Level up/down Red LED Level 1-15	Not available	Power On
Compliance with Voluntary Standards	UL 60601-1, EN60601-1-2, EN 60601-1-11, EN60601-2-10 EN ISO 13485	MDD (93/42EEC), EN 60601-1, EN60601-1-2, EN 60601-1-11, EN60601-2-10	EN 60601-1,EN60601-1-2, EN60601-2-10 EN ISO 13485
Compliance with 21 CFR 898*	Yes	Yes	Yes
Housing Materials and Construction	Casing/body ABS + PET, contacts NBR	Casing/body ABS, footpads NBR	Casing/body ABS Medical Grade Silicon, contacts

		DK Electronics, LLC FlowKeepers®	Actegy Ltd. Revitive IX® (OTC)	HiVox Biotek, Inc. Rapid Relief™ Pennypad PP-904 (OTC)
Maximum output voltage (V) (±20%)	@ 500 Ω @ 2 kΩ @ 10 kΩ	166V 252V 290V	32V Not Available Not Available	57.6V 89.6V 96.0V
Maximum output current (±20%)	@ 500 Ω @ 2 kΩ @ 10 kΩ	332mA 126mA 29mA	10-14mA Not Available Not Available	115.2mA 44.8mA 9.6mA
Pulse Duration (μs)		150 μs +150 μs ±10%	Not Available	200 μs
Frequency (Hz)		100mHz ±10%	20-53Hz	2, 5, 40 Hz
Net Charge per Pulse (μC)		0 @500Ω	Not Available	.2304 @500Ω
Maximum Phase Charge (μC)		2.25 @500Ω	Not Available	23.04 @500Ω
Maximum Current Density (mA/cm^2)		0.789 mA@500Ω	Not Available	2.828 @500Ω
Maximum Power Density (< 0.25 W/cm^2)		0.00177 mW/cm2@ 500Ω	Not Available	0.163 W/cm^2 @500Ω
Burst Mode		No	Not Available	No

DISCUSSION:

The predicate device, Revitive IX® (OTC) is similar to the subject device in the following ways:

1. It provides the same kind of muscle stimulation for the same indications
2. It delivers similar pulsed symmetric biphasic bipolar electric wave.

The main differences among the predicate devices are:

1. FlowKeepers® application is restricted to the calf muscles
2. FlowKeepers® is powered by DC delivered from a small Li+ coin battery and not by AC and a transformer.
3. FlowKeepers® pulse frequency is much smaller (0.2% -0.5%) compared to the predicate device, however, the difference does not impact the safety or effectiveness relative to other Powered Muscle Stimulators and TENS devices operating under these specifications
4. FlowKeepers® is a much smaller and lighter device compared to the predicate device (2% of weight)
5. FlowKeepers® parameters such as maximum output voltage and current, frequency, and pulse duration, although not exactly similar to these particular predicates, do not adversely impact safety or effectiveness. FlowKeepers® parameters are similar to cleared device K160508.

CONCLUSION:

The subject device, FlowKeepers®, is as safe and effective as, and functions in a manner equivalent to the predicate device. The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device identified in the submission. Thus the subject device is substantially equivalent to the predicate device.