DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 23, 2015

Actegy, Ltd
% John J. Smith, MD, JD
Regulatory Counsel
Hogan Lovells US LLP
Columbia Square 555 13th Street, NW
Washington, DC 20004

Re: K143207
Trade/Device Name: Revitive IX (OTC)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX, NUH
Dated: November 7, 2014
Received: November 7, 2014

Dear Dr. Smith,

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,

Felipe Aguel -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 on last page

510(k) Number *(if known)*

K143207

Device Name

Revitive IX (OTC)

Indications for Use *(Describe)*

- *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.*

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) X Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Actegy's Revitive IX (OTC)

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

Actegy Ltd.
Reflex
Cain Road
Bracknell
Berkshire, RG12 1HL
UK

Phone: +44(0) 1344 636 940
Facsimile: +44(0) 8452 255 612

Contact Person: Angela Glover
Date Prepared: March 18, 2015

Name of Device and Name/Address of Sponsor

Revitive IX (OTC) - Model: RIX

Actegy Ltd.
Reflex
Cain Road
Bracknell
Berkshire, RG12 1HL
UK

Common or Usual Name

Muscle Stimulator, Neuromuscular electrical stimulation (NMES) device

Classification Name

Powered muscle stimulator for muscle conditioning, 21 C.F.R. § 890.5850, product code NGX/NUH

Predicate Devices

OTC EMS Stimulator Model MT1001 Shenzhen Dongdixin Technology Co. Ltd (K133965)
Prospera OTC TENS Electronic Pulse Massager – PL009 (K122744)
Revitive IX (RX), Model: RIX Actegy Ltd. (K123354)

Device Description

The Revitive IX (OTC) consists of foot pads and/or electrode pads that deliver electrical stimulation to the lower limb muscles, electrode pads may also deliver electrical stimulation to muscles in the shoulder, waist, back and arms; an optional feature that allows for ankle movement during stimulation; a remote control; dust protectors for the electrode pads; and a user interface. Replacement electrode pads are available separately under 510(k) K132588.

Revitive IX (OTC) is a neuromuscular electrical stimulation (NMES) device that applies electrical impulses that are of sufficient intensity to produce an artificial contraction of the muscle tissue. The device delivers electrical stimulation to the lower limb muscles through foot pads and/or through electrode pads which may be positioned on the lower limb, waist, back or arms. The foot pads are made of conductive black nitrile butyl rubber (NBR) containing carbon, while the electrode pads are made from conductive carbon film coated with an adhesive hydrogel on a cloth backing. It has an optional IsoRocker™ feature that allows ankle movement during stimulation. When enabled, the IsoRocker™ allows Revitive IX (OTC) to tilt back and forth as the muscles contract and relax. The main body of the device is constructed from ABS plastic.

The Revitive IX (OTC) is intended for multiple uses in the home environment and is not provided sterile. The software included in the device controls the pulses generated by the device to stimulate the muscle. The software allows the device to generate various different shapes of pulses with different repetition rates, duration and magnitude. The Revitive IX (OTC) utilizes standard household AC/DC power supply with a 5V DC power adaptor.

Intended Use / Indications for Use

The Revitive IX (OTC) is intended to be used for electrical stimulation of the muscles of the lower leg for the purposes of supporting muscle function, and supporting and improving blood circulation. In addition Revitive IX (OTC) is intended to be used for electrical stimulation of sore and aching muscles to relieve pain. The device is intended for home use for 30 minutes per treatment with a maximum of 3 hours treatment time per day as required.

Revitive IX (OTC) is indicated for:

- *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.*

Technological Characteristics

The Revitive IX (OTC) is a mid-frequency (20-53Hz) Electrical Muscle Stimulator providing pulsed symmetrical biphasic, rectangular and bipolar waveforms utilizing Conductive Footpads & Self Adhesive Cutaneous Electrodes and rocker feature. The device provides an output current of 10-14mA@500Ω r.m.s. and maximum output voltage of 32V@500Ω. Intensity is controlled via the user

interface in 1-99 incremental steps. The duration of the treatment session can be set between 1 and 60 minutes.

Performance Data

Biocompatibility and electromagnetic compatibility and safety testing, and other performance testing were conducted in accordance with the following standards:

ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices. Tests for irritation and skin sensitization
BS EN 60601-1	Medical electrical equipment. General requirements for basic safety and essential performance
BS EN 60601-1-2	Medical electrical equipment - part 1-2: general requirements for safety - collateral standard: electromagnetic compatibility - requirements and tests
EN 60601-2-10	Medical Electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
BS EN 60601-1-11	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.

In all instances, the Revitive IX (OTC) functioned as intended and the results observed were as expected.

A Usability study was conducted to determine that the intended users can identify they are appropriate users of the device and to assess whether they can operate the device in a safe and effective manner based on their reading and following the directions for use contained in the device labeling. The Revitive IX (OTC) summative protocol design, conduct, and analysis followed FDA's human factors draft guidance for industry entitled, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design* (June 22, 2011). In summary, it was established that the Revitive IX (OTC) device, as labeled, is safe and effective in the hands of the intended population and therefore is suitable for Over-The- Counter use.

Substantial Equivalence

The Revitive IX (OTC) is as safe and effective as its predicate devices. The Revitive IX (OTC) has the same technological characteristics, and principles of operation and similar indications and intended uses, as its predicate devices. The differences in Indications between the Revitive IX (OTC) and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Revitive IX (OTC) is as safe and effective as the predicate devices and is suitable for Over-The- Counter use. Thus, the Revitive IX (OTC) is substantially equivalent.

ACTEGY LTD'S

REVITIVE IX (OTC)

SUBSTANTIAL EQUIVALENCE CHART

	Revitive IX (OTC)	OTC EMS Stimulator	OTC TENS Electronic Pulse Massager – PL009	Revitive IX (Rx)
	Candidate	Primary Predicate	Secondary Predicate	Secondary Predicate
510(k) Number	TBD	K133965	K122744	K123354
Device Name, Model	REVITIVE IX (OTC), RIX	OTC EMS Stimulator, MT1001	OTC TENS Electronic Pulse Massager – PL009	REVITIVE IX (RX), RIX
Product Code:	NGX/NUH	NGX	NUH/NGX	IPF
Intended Use	Intended for electrical stimulation of the lower leg and other muscles for various indications	Intended for electrical stimulation of the lower leg for various indications	Intended for electrical stimulation of tired and sore muscles	Intended for electrical stimulation of the lower leg for various indications
Indications for Use	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 OTC EMS stimulator MT1001 is intended to stimulate healthy muscles of the lower extremity in order to temporarily increase local blood circulation and to stimulate healthy muscles in order to improve and facilitate muscle performance.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household activities.	1. Relaxation of muscle spasms; 2. Prevention or retardation of disuse atrophy; 3. Increasing local blood circulation; 4. Muscle re-education; 5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and 6. Maintaining or increasing range of motion.
Technological Characteristics	Mid Frequency (20-53Hz) Electrical Muscle Stimulator providing pulsed symmetrical biphasic, rectangular and bipolar waveforms utilizing Conductive Footpads & Self Adhesive Cutaneous Electrodes and rocker feature	Mid Frequency (10-36Hz) Electrical Muscle Stimulator providing pulsed symmetrical biphasic, rectangular and bipolar waveforms utilizing Conductive Footpads & Self Adhesive Cutaneous Electrodes and rocker feature	Mid Frequency (1-63Hz) Electrical Muscle Stimulator providing pulsed monophasic, rectangular waveforms utilizing Self Adhesive Cutaneous Electrodes	Mid Frequency (20-53Hz) Electrical Muscle Stimulator providing pulsed symmetrical biphasic, rectangular and bipolar waveforms utilizing Conductive Footpads & Self Adhesive Cutaneous Electrodes and rocker feature
Accessories	Self Adhesive Cutaneous Electrodes	Self Adhesive Cutaneous Electrodes	Self Adhesive Cutaneous Electrodes	Self Adhesive Cutaneous Electrodes

	Revitive IX (OTC)	OTC EMS Stimulator	OTC TENS Electronic Pulse Massager – PL009	Revitive IX (Rx)
Manufacturer	Actegy Ltd	Shenzhen Dongdixin Technology Co. Ltd.	Prospera Corporation	Actegy Ltd
Dimensions (mm) [W x H x D]	ø360mm x 75mm	427.3 x 416.5 x 103.7mm	2.24 x 7.80 x 0.91in	ø360mm x 75mm
Weight	1725g (not including PSU)	1910g (device only, excluding batteries)	8.21 oz	1725g (not including PSU)
Power Source(s)	Power adaptor Input: 100-240V, 50/60Hz, 0.18A. Output: 5.0Vdc, 1.0A	Power adaptor Input: 100-240V, 50/60Hz, Output: 6.0Vdc, 300mA Or 6.0Vdc, 4xC batteries	6V battery	Power adaptor Input: 100-240V, 50/60Hz, 0.18A. Output: 5.0Vdc, 1.0A
Safety Features	Automatic Shut off, Override Control	Automatic Shut off, Override Control	Automatic Shut off, Override Control	Automatic Shut off, Override Control
Biocompatibility	Yes	Unknown	Yes	Yes
Number of Output Modes	1	1	3	1
Number of Output Channels	2 (1 for Foot, 1 for body pads)	3 (2 for foot, 1 for body)	2	2 (1 for Foot, 1 for body pads)
Software/Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes
Voltage/Current Level?	Yes: 1-99 intensity indicator	Yes: 1-99 intensity indicator	Yes: 1-10 intensity dial	Yes: 1-99 intensity indicator
Timer Range (minutes)	1 to 60 minutes	1 – 99 minutes	15 minutes	1 to 60 minutes
Compliance with Voluntary Standards?	MDD (93/42EEC),EN 60601-1, EN60601-1-2, EN 60601-1-11, EN60601-2-10	Unknown	IEC60601-1; IEC60601-1-2; IEC60601-2-10	MDD (93/42EEC),EN 60601-1, EN60601-1-2, EN 60601-1-11, EN60601-2-10
Compliance with 21 CFR 898?	Yes	Unknown	Yes	Yes
Housing Materials and Construction	Casing/body ABS, footpads NBR	Unknown	Enclosure ABS	Casing/body ABS, footpads NBR
Sterilization	Not provided sterile	Not provided sterile	Not provided sterile	Not provided sterile
Biocompatibility	Yes	Unknown	Yes	Yes