K 123354

510(k) SUMMARY
Actegy's Revitive IX

JUN 2 8 2013

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

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Date Prepared: June 27, 2013

Name of Device and Name/Address of Sponsor

Revitive IX

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UK

Common or Usual Name

Muscle Stimulator, Neuromuscular electrical stimulation (NMES) device

Classification Name

Powered muscle stimulator, 21 C.F.R. § 890.5850, Product code IPF

Predicate Devices

IF 3Wave Interferential Stimulator System, Model 711 OS, Compex Technologies, Inc. (K050046)
Lifecare Garment Electrodes, Everyway Medical Instruments Co. Ltd. (K103719)

Intended Use / Indications for Use

The Revitive IX is indicated for:

- Relaxation of muscle spasms;
- Prevention or retardation of disuse atrophy;
- Increasing local blood circulation;
- Muscle re-education;
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
- Maintaining or increasing range of motion.

Technological Characteristics

The Revitive IX consists of foot pads and/or electrode pads that deliver electrical stimulation to the muscles; an optional feature that allows for ankle movement during stimulation (IsoRocker); a remote control; and a user interface. See the table below for a technological comparison with the predicate IF 3Wave.

Both Revitive IX and Compex IF 3Wave are mid-frequency (20-80Hz) muscle stimulator devices with biphasic pulses, and both operate in a range which balances between comfort and effective contractions. While there are minor differences in the values for certain of the technological features, the key parameters of the Revitive IX and Compex IF 3Wave are within the same range.

Performance Data

Biocompatibility and electromagnetic compatibility and safety testing, and other performance testing were conducted. In all instances, the Revitive IX functioned as intended and the results observed were as expected.

Substantial Equivalence

The Revitive IX is as safe and effective as the IF 3Wave Interferential Stimulator System and the Lifecare Garment Electrodes. The Revitive IX has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Revitive IX and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Revitive IX is as safe and effective as the predicate devices. Thus, the Revitive IX is substantially equivalent.

Basic Unit Characteristics		
	Compex IF 3Wave - NMES mode	Revitive IX
510(k) Number	K050046	
Device Name, Model	IF 3Wave Model 7110S	REVITIVE IX, RIX
Manufacturer	Compex Technologies, Inc	Actegy Ltd
Power Source(s)	3.6Vdc Lithium Ion Polymer rechargeable battery, 3000mAh	Power adaptor Input: 100-240V, 50/60Hz, 0.18A. Output: 5.0Vdc, 1.0A
Method of Line Current Isolation	Transformers isolation	Transformers isolation

Basic Unit Characteristics		
	Compex IF 3Wave - NMES mode	Revitive IX
Patient Leakage Current2		
Normal condition (µA)	<0.1µA (*)	Patient leakage: 6.21µA max Enclosure leakage: 5.99µA max
Single fault condition (µA)	2.4 µA (*)	Patient leakage: 8.36µA max Enclosure leakage: 7.95µA max
Number of Output Modes	3 + Combo (IF/NMES)	1
Number of Output Channels	2	2 (1 for sole, 1 for body pads)
Synchronous or Alternating?	Alternating	Alternating
Method of Channel Isolation	Transformer	Transformer
Regulated Current or Regulated Voltage?	Regulated voltage up to 150V	Regulated voltage up to 150V
Software/Firmware/Microprocessor Control?	Yes	Yes
Automatic Overload Trip?	No	No
Automatic No-Load Trip?	Yes	No
Automatic Shut Off?	Yes	Yes
Patient Override Control?	Yes	Yes
Indicator Display:		
On/Off Status?	Yes	Yes
Low Battery	Yes	n/a
Voltage/Current Level?	Yes (0 to 100V)	Yes (0V to 150V)
Timer Range (minutes)	15 to 30 mins (NMES pre-set modes)	1 to 60 mins
Compliance with Voluntary Standards?	UL 60601-1, CSA C22.2 No.601-1-M90	EMDD (93/42EEC),EN60601-1-2:2007
Compliance* with 21 CFR 898? *(*Becomes mandatory beginning May 9, 2000)*	21 CFR Part 898 (*)	Complies
Weight	323g with battery	1725g (not including PSU)
Dimensions (mm) [W x H x D]	98.5mm x 160mm x 33.5mm	ø360mm x 75mm overall height
Housing Materials and Construction	Unknown	Casing/body ABS, footpads NBR

(*) Refer to Compex 510(k) application K050046

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

June 28, 2013

Actegy Ltd.
c/o John J. Smith, M.D., J.D.
Hogan Lovells US LLP
553 13th Street NW
Washington, DC 20004

Re: K123354
Trade/Device Name: Revitive IX
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: May 28, 2013
Received: May 28, 2013

Dear Dr. John 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123354

Device Name: Revitive IX

Indications For Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123354