

**Section 4: 510(k) Summary of Safety and Effectiveness**

**Date of Summary Preparation:** May 5, 2009

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Product	Product Code	Regulation and Classification Name
Compex® Rehab	IPF	stimulator, muscle, powered (21 CFR 890.5850)

**Predicate Device:** Globus Genesy 1100 Electro-Stimulator (K071431) with the following intended use:

The Globus Genesy 1100 Electro-stimulator should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. It is intended to be used with NMES, Russian, TENS and Interferential Premodulated Currents (IFC) to obtain the following:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

Additional Indications for Microcurrent, Interferential Premodulated Currents (IFC), NMES and TENS waveforms:

- Management of chronic, intractable pain
- Post-traumatic acute pain
- Post-surgical acute pain
- Immediate post-surgical stimulation of muscles to prevent venous thrombosis

**Indications for Use:**

The Compex® Rehab is an adjunctive multifunction electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES).

The Compex® Rehab is indicated for the following conditions:

- Re-educating muscles
- Relaxation of muscle spasm
- Increasing local blood circulation
- Retarding or preventing disuse atrophy
- Maintaining or increasing range of motion

**Product Description:**

The Compex® Rehab system consists of the following components:

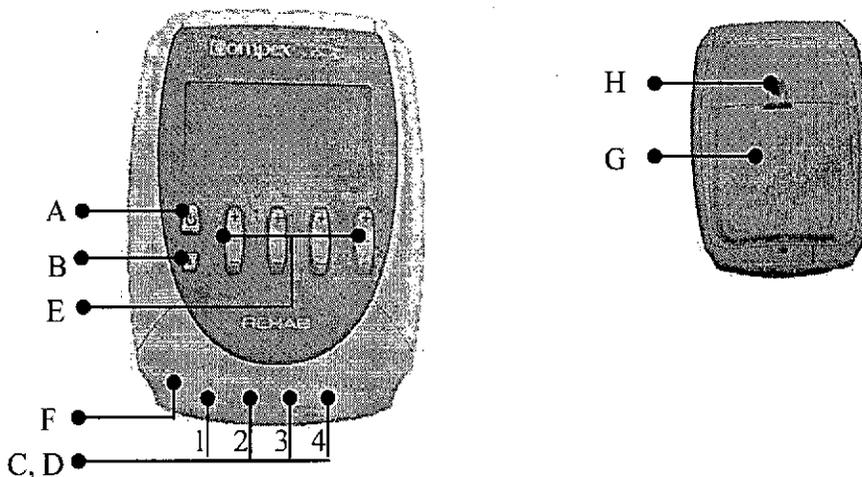
- 1x Stimulator
- 1x Wire Set
- 2x Small Performance Snap Electrode package
- 2x Large Performance Snap Electrode package
- 1x Fast Charger
- 1x Belt clip
- 1x User Manual

These components are packaged together in a carrying case.

The stimulator is a microprocessor controlled 4 channels neuro-muscular electro-stimulator. The stimulator drives each output channel independently based upon the parameters pre-defined for a program selected by the user. The user operates the device through a User Interface (UI) consisting of a graphic LCD, keypad controls and supporting software. The User Interface is made up of four (4) different menus that allow the following functions:

- Options Menu: set up the device, e.g. operating languages, LCD contrast, LCD backlight, Audio output level;
- Body Area Menu: select a desired muscle group, e.g. Shoulder, Hip or Knee;
- Treatments Menu: select a preset program, e.g. Massage, Endurance, Strength;
- Stimulation Menu: select lead wire channels and adjust the stimulation intensities.

**Figure 1 Stimulator**



- A On/Off button
- B "i" button used to increase stimulation energies in several channels simultaneously
- C Sockets for the 4 stimulation cables
- D Stimulation cables
  - Channel 1 = blue
  - Channel 2 = green
  - Channel 3 = yellow
  - Channel 4 = red
- E +/- buttons for the 4 stimulation channels
- F Socket for the charger (slide the red cover to the right to free the charger connector while inserting the charger pin)
- G Rechargeable battery compartment
- H Belt clip socket

The stimulator is housed in a molded portable plastic case with a viewable LCD display, an accessible keypad, and accessible battery storage compartment. The case shape is rectangular.

The LCD is located on the upper half of the rectangular face of the device, above the keypad. The display is a graphic display capable of showing alpha numeric characters (including lower case characters), most standard ASCII symbols, and graphics appropriate to assist the user in selecting a desirable program. The LCD is used to display system information to the user.

The device is equipped with a keypad composed of push buttons which are located below the LCD. The function for each button is defined by a symbol on the LCD corresponding to the button immediately below it.

Power for the device is provided from a 4.8 Volt rechargeable Ni-MH battery pack. The power source is housed behind an operator access panel on the back of the device cover.

Each of the four (4) lead wires will connect the output of the stimulator to each of the electrodes for each respective output channel. Each lead wire will be connected to the stimulator using a high friction, and forced fitting, mechanically shielded connector. Electrode connection is a mechanically shielded snap connector (compliant with the 21 CFR §898.12 PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES).

Each electrode set requires a lead/connector assembly. The electrode connector is compatible with the cable connector. Up to four Active/Passive sets of electrodes are required.

The electrodes (non sterile electrodes) are applied parts which conform to the BF classification of the IEC60601-1 standard and the particular safety standard for nerves and muscles stimulators: IEC60601-2-10.

For patient safety, the device is designed to prohibit use of the device on patients while the battery is being charged. A red plastic cover inside the charging socket blocks the charger pin when the lead wires are still connected to the device. Unplugging the lead wire cables unlocks the red plastic cover and allows the charger pin plug in the charging socket. Connecting a charger to the stimulator automatically starts the charging procedure. A battery symbol on the LCD indicates the status of the battery charging.

The battery pack of the stimulator is charged by a switching adapter which supplies an output current of 1.4 A +/-100 mA and an output voltage of 9V DC +/- 2%. The primary plug is an American 2 pin AC

type able to handle input voltage from 90 to 240V AC and at a maximum input current of 0.5 A. The secondary plug on the stimulator is a straight jack plug with the following dimensions, outer diameter: 3.5 mm, inner diameter: 1.3 mm and length: 9 mm. The charger has a short circuit protection. Maximum dimensions of the charger are 72 x 52 x 35 mm.

### **Program Descriptions:**

The Compex Rehab provides three muscle stimulation training programs which correspond to target muscle groups (Shoulder, Knee, Hip) of the patient intended for use during rehabilitation. These rehabilitation programs are:

- Massage
- Endurance
- Strength

#### **1. Massage**

The Compex Rehab Massage program is intended to relax muscle spasm, reduce the muscular spasticity, and enable the target muscles to contract effectively.

This program is recommended for use as needed before and after the surgery as prescribed by your medical professionals.

#### **2. Endurance**

The Compex Rehab Endurance program focuses on activating an average medium working level on muscle fibers. This working level is maintained over a long time period (25 minutes per session). The Endurance program particularly activates the aerobic metabolism of the fibers during the stimulation session. The purpose is to increase the time for the muscle to maintain a medium level of working power or the average power level for extended periods of time.

This program is recommended for use before and after the surgery as prescribed by your medical professionals.

#### **3. Strength**

The Compex Rehab Strength program imposes a high and instantaneous power working level on muscle fibers. These contractions are separated by long periods of rest. The result is an average medium power working level (+ 20 minutes). This program is intended to increase the maximum strength of muscle isometric contraction. This program targets the muscle fibers that are typically afflicted with immediate atrophy after injury or/and surgery.

This program is recommended for use only after having completed at least 10 sessions of previous the Endurance program as prescribed by your medical professionals.

**Substantial Equivalence:** When compared to the predicated device, Globus Gensy 1100 Electro-Stimulator, the Compex® Rehab has the same intended use, output mode (NMES), NMES output parameters, and energy delivered. In addition, any differences in their technological characteristics are explained to demonstrate in this submission that these differences do not raise any new questions of safety or effectiveness. Therefore, Compex® Rehab is substantially equivalent to the predicate marketed device, Globus Gensy 1100 Electro-Stimulator.



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Vice President of Global Regulatory Affairs  
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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K090632  
Trade Name: Compex® Rehab  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered muscle stimulator  
Regulatory Class: II  
Product Code: IPF  
Dated: May 5, 2009  
Received: May 9, 2008

Dear Ms. York:

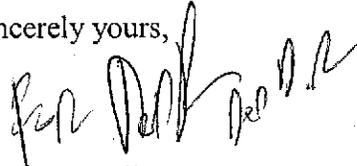
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE**

Device Name: Compex® Rehab

510(k) Number if known: \_\_\_\_\_

The Compex® Rehab is an adjunctive multifunction electrotherapy device with various treatment modes that allow for neuromuscular electrical stimulation (NMES).

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Prescription Use  (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of Surgical, Orthopedic,  
 and Restorative Devices

510(k) Number K090632