APR 3 0 2007

510(k) Summary
for
Globus Premium Sport and Fitness Muscle Stimulators

1. SPONSOR

Domino S.r.l.
Via San Felice, 4
31020 San Vendemiano (TV)
Italy

Contact Person: Giovanni Ciriani
Telephone: 860-539-1309

Date Prepared: March 26, 2006

2. DEVICE NAME

Proprietary Name:	Globus Premium Sport and Fitness Muscle Stimulator
Common/Usual Name:	Electric Muscle Stimulator
Classification Name:	Powered muscle stimulator

3. PREDICATE DEVICES

Compex Sport Stimulator Device K011880

4. DEVICE DESCRIPTION

The Globus Premium Sport and Fitness Devices are programmable muscle stimulators. Each device in the family comes with a menu to navigate between different stimulation programs. The Stimulation Programs have been subdivided in menus and submenus to facilitate use for various types of uses.

The Globus Premium Stimulators electrical impulses trigger action potentials on motor neurons of motor nerves. These excitations are transmitted via the motor end-plate to the muscle fibers, where they generate mechanical responses that result in muscle work. Depending on the electrical impulse parameters (current intensity, frequency, shape of the impulse, duration of contraction, duration of rest, total session duration) different types of muscle work can be performed. This

work is able to improve or facilitate muscle performance, and may therefore be considered a muscle training technique.

The Globus Premium family models include the Globus Premium Sport and the Globus Premium Fitness. The configurations differ in the navigation menus that allow the user to select the pre-stored electrostimulation programs offered, but offer technically-identical electrostimulations. The core of the Globus Premium device is a constant-current generator; a transformer guarantees insulation between outlet current utilized for the battery charger, and the circuits utilized for stimulation current. A micro-processor elaborates the menu selections and drives the constant-current generator that originates the electrical impulses for the electrostimulation. This is accomplished according to the parameters stored for that particular program. The user can regulate the current continuously from 0-120 mA.

5. INTENDED USE

The Globus Premium Sport and Fitness Muscle Stimulators are intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Globus Premium Sport and Fitness family of muscle stimulation devices are not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Globus Premium training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Domino S.r.l. Globus Premium Sport and Fitness device and the Compex Sport Stimulator are similar in design and function. All of the devices offer a biphasic waveform, rectangular, symmetrical and compensated and a beat frequency in the range of 1-120 Hz. The Globus and predicate devices are software driven powered muscle stimulator units that provide the user with a treatment program for healthy muscles.

The Globus Premium and the Compex Sport devices are all very similar in design configuration, technical characteristics and performance. The Globus Premium devices maximum current output and maximum electric charge are very similar to the predicate device. The only significant difference between the Globus Premium Sport and Fitness and the predicate device is that the Globus Premium devices can perform stimulation on different muscular groups of the same subject.

This is accomplished by providing two different stimulation currents on different channels e.g. while stimulating the legs, it can also stimulate arms at the same time. The proposed Globus Premium Sport and Fitness device architecture, safety features and isolation modes are substantially similar to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Domino S.r.l.
% Globus Sport and Health Technologies, LLC
Mr. Giovanni M. Ciriani, B.A.
Managing Partner
18 Eustace Drive
West Hartford, Connecticut 06110

APR 30 2007

Re: K061632
Trade/Device Name: Globus Premium Sport and Fitness Muscle Stimulators
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 26, 2007
Received: March 28, 2007

Dear Mr. Ciriani:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K061632

Device Name: Globus Premium Sport and Fitness Muscle Stimulators

Indications For Use:

The Globus Premium Sport and the Globus Premium Fitness Muscle Stimulators are intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Globus Premium Sport and Globus Premium Fitness Muscle Stimulators are not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Globus Premium training programs are designed for injured or ailing muscles and their use on such muscles is contraindicated

Prescription Use _____ AND/OR Over-the-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061632