

FEB - 5 2010

JK092142



PREMARKET NOTIFICATION 510(K)
SUBMISSION

Body Control System
Buttock's Short
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5. 510(K) SUMMARY

[As Required by 21 CFR 807.92]
Summary of Safety and Effectiveness

| | | |
|---|--|--|
| 1 | Submitter | SPORT-ELEC S.A. Route de Rouen BP 35 27520 Bourgtheroulde France |
| | Contact Person | Karine Coral / Jean Philippe Broucke Phone number : (+33) 2 32 96 50 50 Fax number : (+33) 2 32 96 50 59 |
| | Preparation date | January 24 th 2009 |
| 2 | Device name | Body Control System "BS" |
| | Trade Name | SPORT-ELEC® |
| | Common Name | Muscle stimulator |
| | Code product and classification name | Stimulator, muscle, powered for muscle conditioning (NGX) 21 CFR Section 890.5850 Powered Muscle Stimulator |
| 3 | Predicate devices | SPORT-ELEC Body Control System, manufactured by Sport-Elec REF BCS K 081026 Cleared Nov 5 th 2008 and: Slendertone System Short K070142 Cleared March 23 th 2007 |
| 4 | Description | <p>Body Control System "BS" is a 2 channel battery operated muscle stimulation system specifically designed to exercise the buttocks' muscles. It comprises namely an electronic stimulator module which generates the required stimulation signals.</p> <p>Body Control System "BS" comprises a short with integral electrodes, which connects the signals from the stimulator to the skin. The built-in electrodes are located on the inner surface of the accessories.</p> <p>The product is supplied with the cream VC 57B/53 -148, a User's Guide and a carry case.</p> |
| | Explanation of how the device operates | <p>Power is derived from 3 batteries located in a compartment protected by a removable battery cover.</p> <p>The electrodes are integrated in the inner surface of the short. The garment is worn as shown on picture.</p> <p>There is no current passed from side to side. The user cannot access the wiring or connectors within the short.</p> |
| | Intended use | <p>The Body Control "BS" is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes;</p> <ul style="list-style-type: none"> - Improvement of muscle tone of the muscles of buttocks. |

- 5 Performance data Testing was carried out to assure compliance with recognized electrical safety standards:
IEC 60601-1 and -2-10 standards for electrical safety
IEC 60601-1-2 standard for electromagnetic compatibility
IEC 60601-1-4 standard for the software. (ISO 14971 : 2007)
Performance data were also verified versus the requirements of the FDA Guidance for Pre Market Submissions and for Software contained in Medical Devices.
- 6 Substantial equivalence summary The technological characteristics, features, specifications, materials, mode of operation, and intended use of the Body Control System Short device are substantially equivalent to the predicate devices quoted above.
The differences that exist between the devices do not raise new issues of safety or effectiveness regarding the Body Control System Device.
The short of the Body Control System "BS" use the same as the BCS training system and Slendertone System Short in it's delivery of the stimulation signal and has similar parameter setting. There are similar restrictions between the two devices in that electrode positioning is governed by and is integrated to the garment.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

FEB - 5 2010

Sport-Elec
% Registrar Corp
Kimberly Jones, Ph.D.
Senior Regulatory Specialist
Compliance Department
144 Research Drive
Hampton, Virginia 23666

Re: K092142
Trade Name: Sport-Elec Body Control System "BS"
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulation Class: Class II
Product Code: NGX
Dated: January 21, 2010
Received: January 25, 2010

Dear Dr. Jones:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,



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

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Body Control System "BS"

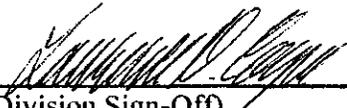
Indications for Use: Body Control System is indicated for the improvement of buttocks muscles tone, for strengthening of buttocks muscles.

Contraindicated use on injured or otherwise impaired muscles

Not intended for use in any therapy or for the treatment of any medical conditions or diseases

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

 FOR M. MELKERSON
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number: K092142