K071026

5. 510(K) SUMMARY

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

NOV - 5 2008

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	Jan 10, 2008
2	**Device name**	Body Control
	Trade Name	SPORT-ELEC®
	Common Name	Powered Muscle stimulator
	Product code and classification name	Stimulator, muscle, powered for muscle conditioning (NGX) 21 CFR Section 890.5850
3	**Predicate devices**	SPORT-ELEC ABDOMINAL Training System, manufactured by Sport-Elec REF CT 5 K061914 Cleared July 26th 2007
4	**Description**	Body Control is a 2 channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It is comprised of an electronic stimulator module which generates the required stimulation signals. Body Control is comprised of a belt 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 belts . The product is supplied with the cream VC 57B/53 -148, a User's Guide and a carry case.
	Explanation of how the device operates	Power is derived from 3 batteries located in a compartment protected by a removable battery cover for the Body Control. The electrodes are integrated in the inner surface of the belt. The garment is worn secured by hooks and loops fastening patches. There is no current passed from side to side. The user cannot access the wiring or connectors within the belt.

	Intended use	The Body Control device is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes; - Improvement of muscle tone of the muscles in the abdomen.
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. Performance data was 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 device is substantially equivalent to the predicate device quoted above. The differences that exist between the devices do not raise new issues of safety or effectiveness regarding the Body Control Device. The Body Control is the same as the CT5 Abdominal training system in its delivery of the stimulation signal and has similar parameter settings. There are similar restrictions between the two devices in that electrode positioning is governed by and is integrated into the garment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sport-Elect S.A.
% FDA Registrar Corp
Ms. Sharon Scannell
Senior Compliance Specialist
144 Research Drive
Hampton, Virginia 23666

NOV - 5 2008

Re: K081026
Trade Name: Body Control
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 15, 2008
Received: October 27, 2008

Dear Ms. Scannell:

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 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological 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

Indications for Use: Body Control is indicated for the improvement of muscle tone, for strengthening of muscles and for the development of firmer muscles. It is indicated for use on the abdominal 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 (Part 21 CFR 801 Subpart D) ___ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) ___ X___

(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 K081026