K102295



# 510(k) Summary

FEB 18 2011

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

**1. Submitter's Information**

510(k) Owner's Name: Leto Enterprises Incorporation
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Contact Person: Patrick Braun
Email: pb@red-lemon.net

➢ **Contact Person of the Submission:**

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**2. Device Information**

| | |
|---|---|
| Trade Name: | X2ABS Dual Channel Fitness Belt |
| Common Name: | Powered muscle stimulator |
| Classification name: | Stimulator, Muscle, Powered, For muscle conditioning |
| Review Panel: | Physical Medicine |
| Product Code: | NGX |

| | |
|---|---|
| Regulation Class: | II |
| Regulation Number: | 890.5850 |

**3. Predicate Device Information**

| | |
|---|---|
| Submitter: | SPORT-ELEC S.A. |
| Device Name: | Body Control |
| 510(K) Number: | K081026 |

**4. Device description**

X2ABS Dual Channel Fitness Belt is a two channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It is comprised of an electronic stimulator module for signal generation, a belt for fixation, and four electrodes for signal connection to skin. The built-in electrodes are located on the inner surface of the belts.

Power is derived from 2 batteries located in a compartment protected by a removable battery cover for the Fitness Belt. There is no current passed from side to side. The user cannot access the wiring or connectors within the belt.

The stimulator sends gentle electrical current to targeted muscle group through the electrodes placed on the skin. The parameters of the unit are controlled by the buttons. Its intensity level can be adjustable by user.

**5. Intended Use**

The X2ABS Dual Channel Fitness Belt 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.

**6. Indications for Use**

The X2ABS Dual Channel Fitness Belt 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.

**7. Performance Summary**

Testing has been 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 has been verified according to the requirements of the FDA Guidance for Pre Market Submissions and for Software Contained in Medical Devices.
The waveform test report has also been provided to verify the parameters of the device.

**8. Comparison to predicate device and conclusion**

The technological characteristics, features, specifications, materials, mode of operation, and intended use of X2ABS Dual Channel Fitness Belt is substantially equivalent to the predicate device quoted above.
The differences that exist between the subject device and predicate device do not raise new issues of safety or effectiveness.
The X2ABS Dual Channel Fitness Belt is the same as the Body Control device in its delivery of the stimulation signal and has similar parameter settings. There are similar restrictions between the two devices in the electrode positioning is governed by and is integrated into the garment.

**9. Date of the summary prepared: July 20, 2010**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Leto Enterprises Incorporation
% Ms. Sabrina Wei
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Hong Kong, China 999077

FEB 18 2011

Re: K102295
Trade Name: X2ABS Dual Channel Fitness Belt
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 6, 2011
Received: January 6, 2011

Dear Ms. Wei:

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.

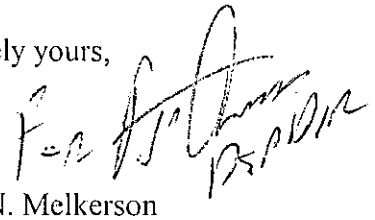
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/ucm115809.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" (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,



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

# Indications for Use

510(k) Number (if known): K102295

Device Name: X2ABS Dual Channel Fitness Belt

Indications for Use:

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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 ___X___ (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



510(k) Number K102295