SEP 1 3 2002

K020429

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2.0 510(K) SUMMARY

2.1 Sponsor Information

Sponsor	The Dezac Group 54-56 Bath Road Cheltenham, Glos. GL53 7HG United Kingdom
Registration	in England No. 2186341
Contact Person	Mr. Kevin Herbert, Project Engineer Phone +44 1242 702300 Fax +44 1242 702301 E-mail kherbert@dezac.co.uk

2.2 Device Name

Trade Name of Device	Ab Belt Pro
Common Name	Muscle Stimulator
Classification name	Powered Muscle Stimulator
Product Code	NGX
Regulation Class	II
Regulation Number	890.5850

2.3 Indications for Use

The Ab Belt Pro device is indicated for use for the improvement of abdominal muscle tone, for strengthening of the abdominal muscles and for developing a firmer abdomen.

2.4 Device Description

The Ab Belt Pro is a single channel battery operated muscle stimulation system specifically designed to exercise the abdominal muscles for the purposes of improving abdominal muscle tone, strengthening the abdominal muscles and developing a firmer abdomen.

It comprises an electronic stimulation controller module which generates the required electrical stimulation signals and an abdominally worn electrode belt which connects the signals from the stimulator to the skin electrodes located on the inner surface of the belt.

The device is supplied with a set of three identical electrodes, a tube of conductive gel, an instruction manual, a set of batteries and a fabric belt extension for fuller figures. Power is derived from three (3) 1.5V AAA batteries located in a compartment protected by a removal battery cover at the rear (belt side) of the device. The central umbilical electrode is common to each of the left and right stimulation circuits.

The electrodes connect mechanically to 'press-studs' mounted on the inner face of the abdominal belt. The studs are presented in such a way that each of the outer electrodes may be rotated about a single common stud to accommodate both inner and outer muscle groups. Only these single common studs of the outer electrodes and the central umbilical electrode are electrically connected to the stimulator unit. This prevents stimulation to the user through a stud, which is not covered by an electrode pad.

The user extends the belt and puts it in a wrapping motion from front to back, closing it at the back using Velcro patches. When the belt is in place the central electrode locates over the umbilicus and the two outer electrodes locate on either side of the body towards the mid axillary line, between the pelvis and the rib cage. It is well known in the art that this electrode positioning is particularly useful for stimulating the abdominal muscles.

The pulsed stimulation current passes between the outer and center electrodes only. There is no current passed from outer electrode to outer electrode. The user has no access to the wiring or connectors as they are stored internally within the belt structure. As a result he or she cannot alter the current path and so the possibilities for misuse are greatly reduced.

2.5 Basis for Substantial Equivalence

Predicate Device

Slendertone™ Flex: K010335 (Class II)

Bio-Medical Research Ltd

c/o Mr. Robert Dormer

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Hyman, Phelps & McNamara, P.C.
700 13th Street NW, Suite 1200
Washington, D.C. 20005

- The Ab Belt Pro device has the same indications for use as the predicate device.
- The Ab Belt Pro device has equivalent technological characteristics and instructions for use, as compared to the predicate device.
- The device meets the mandatory performance standard identified in 21 CFR 898.
- The biocompatibility of the electrodes has been established.
- The conductive gel is a legally-marketed gel cleared through 510(k) number K983964.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Mr. Kevin Herbert
The Dezac Group
54-56 Bath Road
Cheltenham, Glos.
GL53 7HG United Kingdom

Re: K020429
Trade/Device Name: Ab Belt Pro
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 9, 2002
Received: September 10, 2002

Dear Mr. Herbert:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement

510(k) number (if known):	K020429
Device Name:	AbBelt Pro
Sponsor Name:	The Dezac Group
Indications for use:	The AbBelt Pro is indicated for use for improvement of abdominal muscle tone, for strengthening of the abdominal muscles, and for the development of a firmer abdomen.

for Mark N Milhern

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

510(k) Number K020429