NOV 16 2005

K052969

Section 4: 510(k) Summary of Safety and Effectiveness

This summary is submitted in accordance with 21 CFR 807.92

1.	Device Manufacturer: Sponsor	Bio-Medical Research Ltd. Parkmore Business Park West Galway Ireland
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	Title:	Quality Systems Engineer
	Date of Preparation:	October 17, 2005
2.	Trade Name of Device:	Slendertone Gymbody, Type 512-01
	Common Name:	Muscle Stimulator
	Classification Name:	Stimulator, muscle, powered, for muscle conditioning
	Product Code	NGX
3.	Identification of Predicate:	Slendertone Flex, Type 512 Bio-Medical Research Ltd. K010335

4. Description of Device:

Slendertone Gymbody, Type 512-01 is a two-program battery operated muscle stimulation system specifically designed to exercise the abdominal muscles. It is a variant of Slendertone Flex, Type 512 abdominal training system and was developed to provide a lower cost alternative to the consumer.

It comprises of two main components, an electronic stimulator module, which generates the required stimulation signals, and an abdominal electrode belt, which connects the signals from the stimulator to the skin electrodes located on the inner surface of the belt.

The product is supplied with a set of double-sided adhesive electrodes, an instruction manual and a set of batteries. Power is derived from 1 x 9volt battery located in a compartment protected by a removable battery cover.

The 3 pads are attached to the belt covering the 3 metal studs on the inner surface of the belt. The larger pad is placed in the middle, over the umbilicus, and the two side electrodes are located on either side of the body towards the mid axillary line, between the pelvis and the rib cage.

The pulsed stimulation current passes between the side and center electrodes only. There is no current passed from side to side.

5. Technological Comparison

Slendertone Gymbody is a variant of the Slendertone Flex Abdominal Training System and is a lower cost alternative to the consumer.
It has been designed to differ visually from the original device while remaining compliant with all necessary legislative and performance standards. The device's intended use or fundamental scientific technology does not differ from Slendertone Flex, Type 512 (K010335).

Design

Slendertone Gymbody, Type 512-01, is a two channel, three electrode, battery operated muscle stimulation system comprising of two main components, the electronic stimulator module and the electrode belt. The device uses a set of adhesive electrodes to transfer stimulation signals to the skin. This is the same as Slendertone Flex, Type 512.

Slendertone Gymbody, Type 512-01 is a 2 program device whereas Slendertone Flex, Type 512 is a 4 program device. The 2 program levels (1 & 2) are the same as levels 2 and 4 in Slendertone Flex, Type 512.

Slendertone Gymbody, Type 512-01 contains a different user interface from its predicate device Slendertone Flex, Type 512. The LCD user interface present in Slendertone Flex, Type 512 has been changed to a series of LEDS. There is no significant change to the internal control mechanism and principles of operation remain the same. Visual indication of status and functionality are different however and are reflected in the instructions for use. The changes do not impact on the safety or efficacy of the device.

Slendertone Gymbody, Type 512-01 contains a different housing and keypad format from Slendertone Flex, Type 512 . The changes do not impact upon safety or efficacy of the device nor do they impact on indications for use. The fundamental operating principle remains the same.

Material

There are no fundamental changes to materials of construction that could impact on use. Comparative details are outlined in the table below.

Material	Slendertone Flex Type 512	Slendertone Gymbody Type 512-01
Belt	Outer Material 100% Nylon Binding: 82% Nylon/18% Elastene Velcro: 100% Nylon Foam: 100% Polyurethane	Outer Material: 100% Polyester Binding: 82% Nylon, 18% Elastane Velcro: 100% Nylon Foam: 100% Polyurethane
Electrodes	Type 709/710 Hydrogel layer with conductive polymer film 2 x 70mm x 100mm and 1 x 100mm x 100mm	Type 709/710 Hydrogel layer with conductive polymer film 2 x 70mm x 100mm and 1 x 100mm x 100mm
Unit Housing	ABS	ABS
Key Mat	Silicon Rubber	Silicon Rubber
Status Indicator	Liquid Crystal Display	Light Emitting Diodes
Battery Connection	Holster Pin Arrangement	Lead wire with through hole three-pin connector providing both polarizing and latching mechanism.

Chemical Composition
Not applicable

Energy Source
No change in energy type, however Slendertone Gymbody, Type 512-01 utilizes 1 x 9v battery in comparison to 3 x 1.5v batteries in Slendertone Flex, Type 512.

6. Statement of Intended Use and Indications Compared to Predicate
The Slendertone Gymbody, Type 512-01 device that is the subject of this 510(k) Special premarket notification has the same identical intended use and indications for use as the above predicate. It is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation ("EMS") through skin contact electrodes for the purpose of improving abdominal muscle tone, strength and firmness.

7. Clinical Studies
The same technolgical platform and modus operandi is used for the new variant, effectivity of which is borne out in the original clinical trial data submitted for review along with Slendertone Flex, Type 512 (K010335).

8. Safety and Effectiveness
Slendertone Gymbody was designed and evaluated with the BMR Design Control System (Ref: D180). There were no issues regarding the Safety and Effectiveness of the device.

Section 8: Design Control

Risk Management.
A risk analysis was carried out during the design phase of the previously marketed device, Slendertone Flex, Model 512. Since then, the procedure for Risk Management in the company has been upgraded to reflect the requirements of ISO 14971. This new procedure has now been applied to the proposed modified device Slendertone Gymbody Model 512-01 and the full analysis is on file.

Summary of Changes
In this summary we highlight the modifications to the product from the standpoint of risk.

Replacement of LCD by LEDs
All major display functions of the LCD are implemented on the LEDs, except;

> The treatment is digitally timed however the time is not displayed. No safety or efficacy issue is raised since the timer display is a convenience indicator to inform the user on the remaining treatment time.
>
> The stimulus intensity is not digitally displayed, instead 3 LEDs are used to represent 4 levels of stimulation. The stimulus intensity is incremented in 1% steps with each keypress, as it was on the previously marketed device. No safety or efficacy issue is raised here because the stimulus intensity setting is determined by the user's comfort and tolerance level, not by prescription of any particular intensity level. The digital display is a convenience indicator to inform the user about the intensity level they have reached.

Removal of Audible feedback.

The audio indicator was used in the predicate device to provide audio feedback beeps with each keypress and to alert the user when the load sense circuit detected no load. This is a convenience issue with no safety issue since the intensity is reduced to effectively zero when no load is detected. In any case, there was an audio mute function on the predicate model.

Removal of EEPROM
The EEPROM only stored user statistics and preferences on the predicate device, not treatment data. No safety or efficacy issue arises with its removal.

Change to a single amplitude control.
The predicate device has a separate left and right intensity control, however the new device has a single control which controls both left and right. The product is intended to stimulate the abdominal muscles symmetrically, that is, approximately equally on the left and right sides. The predicate device already had a software control which prevented the user selecting gross asymmetry in left and right intensity. No safety or efficacy issue is raised by this change.

Change of battery type.
No safety or efficacy issue arises.

Removal of two programs.
The main working program of the new product, program 2 is identical to program 4 of the predicate device. The other programs have been included to introduce users to the sensation of EMS, with slightly shorter contraction times. No safety or efficacy issue arises.

Change to style of Belt
The spacing, size and design of electrodes are identical so no safety or efficacy issue arises.

Change to Connector linking Controller and Belt
The connector design has changed from an audio jack and socket to an industrial wire to board connector. The connector in the new product is perhaps less convenient to use however it provides the same or greater protection. The arrangement also been certified for compliance to the ISO 60601 standards. Furthermore, since the leadwires are integrated within a belt, the risk is negligible.

A declaration of conformity to design control is included in Appendix 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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NOV 16 2005

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Re: K052969
Trade/Device Name: Slendertone Gymbody, Type 512-01
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 18, 2003
Received: October 21, 2003

Dear Mr. O'Sullivan:

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-__. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting 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 (if known): K052969

Device Name: Slendertone Gymbody, Type 512-01

Indications for Use:

Slendertone Gymbody is indicated for the improvement of abdominal muscle tone, for strengthening of the abdominal muscles and for the development of a firmer abdomen.

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)

(Division Sign-Off) CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K052969