K041359

AUG 2 0 2004

10 510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

10.1 Submitter's Identification:

Body Clock Health Care Ltd
108 George Lane
South Woodford
London
E18 1AD
United Kingdom

Tel: +44 (0)20 8532 9551
Fax: +44 (0)20 8532 9551

Contact: Rashelle Preston
Date Prepared: 18 May 2004

10.2 Name of Device:

Proprietary Name:
I. Body Clock Stimplus Pro
II. Body Clock Stimplus

Common or Usual Name:
TENS unit (Transcutaneous Electrical Nerve Stimulator)

Classification Name:
Stimulator, Nerve, Transcutaneous, For Pain Relief.

10.3 Predicate Device Information:

The Body Clock Stimplus Pro is identical to the Solitens Modified (Stimplus Pro) (**K913522**)
The Body Clock Stimplus is very similar to the Solitens Modified (Stimplus Pro) (**K913522**)

10.4 Device Description:

The TENS devices are used to transmit electrical pulses through the skin to the underlying peripheral nerves to aid in the blocking of the pain signal travelling to the brain.

10.5 Intended Use:

TENS is used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

10.6 Technological Comparison to Predicate Device:

The Body Clock Stimplus Pro is identical to the predicate device (the Solitens Modified - **K913522**). The Body Clock Stimplus is very similar to the predicate device and has technological characteristics that are substantially equivalent to the predicate device.

Each of the units is made from the same mould and feature the same number of function switches. Most of the functions are identical, namely the Intensity Switch, the Power Switch, the Stimulation Switch and the Time Selector Switches. The timer selection on the units differ very slightly. On the Body Clock Stimplus Pro and predicate device, the user can choose to manual, 15 seconds or 30 seconds. On the Body Clock Stimplus, the user can choose between manual, 30 seconds and 60 seconds.

Both units also have switches providing the user with adjustable stimulation control. On the predicate unit and Body Clock Stimplus Pro is the Frequency Switch. On the Body Clock Stimplus, there is a Rhythm Switch.

Each of the units have their remaining features in common, including a low battery indicator, stimulation switch and LED display on the tope of the unit, passive contact plate and battery compartment on the underside of the unit and gold plate tip. In essence the predicate device and the Body Clock Stimplus Pro are almost identical to the Body Clock Stimplus and are technically substantially equivalent.

10.7 Non-clinical Testing:

- All Units are fully CE marked i.e. compliant with **EEC Directive 93/42/EEC Annex V**, classified as "Internally powered Equipment Type BF. They are intended for continuous operation."
- ISO 9002
- ISO 13488
- EN 46002
- EN 60601-1-2:1993 (**EEC Directive 89/336/EEC**)
- IEC 601-1:1988 + A1:1991 + A2:1995
- EN60601-1:90 + A1:93 + A2:95 + A13:96

10.8 Clinical Testing:

Not Applicable as there are no new or innovative aspects that have been introduced.

10.9 Conclusions:

The Body Clock Stimplus Pro and the Body Clock Stimplus have the same intended use and similar technical characteristics to the Solitens Modified (Stimplus Pro) (**K913522**).

The information supplied in this 510(k) illustrate that the device does not pose any new questions of safety and effectiveness. The Body Clock Stimplus is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2004

Ms. Rashelle Preston
Director of Special Projects
Body Clock Health Care Ltd
108 George Lane
South Woodford
London
E18 1AD England

Re: K041359
Trade/Device Name: Body Clock Stimplus and Body Clock Stimplus Pro
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: May 18, 2004
Received: May 21, 2004

Dear Ms. Preston:

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 (301) 594-4659. 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/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

8 Statement of Indications For Use

510 (k) Number (if known): _____

Device Name/s: Body Clock Stimplus Pro
Body Clock Stimplus

Indications For Use:

The Body Clock Stimplus Pro and Body Clock Stimplus are used for the symptomatic relief and management of chronic intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain.

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041359

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 _____

Prescription Use X
(Per 21 CFR 801.109)