10 510(k) Summary

K021846

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
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NOV 2 2 2002

Contact: Jonathan Bash
Date Prepared: May 30th 2002

10.2 Name of Device:

Proprietary Name:
I. 804SIII
II. 804W
III. Libra TENS
IV. 410
V. S-TENS II

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

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

10.3 Predicate Device Information:

The 804SIII, 804W, Libra TENS, 410 and S-TENSII are equivalent to the FUJI TENS 804SIII (**K893874**). The 804W and Libra TENS also have pulse width adjustment. The 410 is also equivalent to the FUJI TENS Myostim 410 (**K853719**)

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 pain signals 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 Devices:

The 804SIII, 804W, Libra TENS, 410 and S-TENS II have basic technological characteristics that are substantially equivalent to the predicate device.

The **804SIII** is identical to the FUJI TENS 804SIII (**K893874**). The **804W** is slightly different to the 804SIII. There is only one dial for pulse rate adjustment with both the left and right channels controlled by the one dial as opposed to having two independent user controls. It is additionally capable of Pulse Width Adjustment. The **Libra TENS** has similar internal workings to the 804W. The only functional difference is a timer switch, which allows the user to leave the unit on for a timed 30 minutes or 60 minutes. The **410** is a single channel unit with one adjustable Pulse Rate dial and one adjustable Output dial. The **S-TENS II** is a single channel unit with one adjustable Pulse Rate dial, one Output dial and a switch option for Burst, Continuous or Modulation.

All units use "shrouded patient cable connector's" to comply with the FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables."

10.7 Non-clinical Testing:

All required sections of the AAMI/ANSI NS-4 Standard were met.
All units pass the required IEC 60601-1:1990 + a1:1993 + A2: 1995 standards.
All units pass the IEC 601-1:1988 + a1:1991 + A2:1995 standards.

10.8 Clinical Testing:

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

10.9 Conclusions:

The 804SIII, 804W, Libra TENS, 410 and S-TENS II have the same intended use and similar technical characteristics as the FUJI TENS 804SIII (**K893874**).

The information supplied in this 510(k) illustrate that the devices do not pose any new questions of safety and effectiveness. The 804SIII, 804W, Libra TENS, 410 and S-TENSII are substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2002

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

Re: K021846
Trade/Device Name: 804SIII
804W
Libra TENS
410
S-TENSIII
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: August 27, 2002
Received: September 3, 2002

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. 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,

Neil R P Ogden 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): K021846

Device Name/s:
804SIII
804W
Libra TENS
410
S-TENSII

Indications For Use:

The 804SIII, 804W, Libra TENS, 410 and S-TENSII 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.

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

510(k) Number K021846