SEP 2 4 2002



# 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: K022076

## 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:** Jonathan Bash
**Date Prepared:** June 19th 2002

## 10.2 Name of Device:

**Proprietary Name:**
I. First Choice
II. First Choice Plus

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

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

## 10.3 Predicate Device Information:

The First Choice and First Choice Plus are equivalent to the FUJI TENS 804SIII (**K893874**). The First Choice Plus also has pulse width adjustment.

## 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 First Choice and First Choice Plus have basic technological characteristics that are substantially equivalent to the predicate device.

The **First Choice** has a slightly lower functionality than the FUJI TENS 804SIII (**K893874**) in that there is only one dial for pulse rate adjustment. This means that both the left and the right channels are controlled by one pulse rate dial as opposed to having two separate dials.

The **First Choice Plus** has identical functionality to the 804SIII except that both the left and the right channels are controlled by one pulse rate dial as opposed to having two separate dials. It also has pulse width adjustment.

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 First Choice and First Choice Plus 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 First Choice and First Choice Plus 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

SEP 24 2002

Mr. Jonathan Bash
Director of IT and Special Projects
Body Clock Health Care Ltd
108 George Lane
South Woodford, London
E18 1AD

Re: K022076
Trade/Device Name: First Choice and First Choice Plus
Regulation Number: 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: June 19, 2002
Received: June 26, 2002

Dear Mr. Bash:

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.

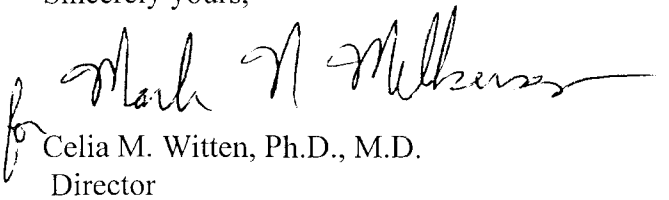
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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):** K022076

**Device Name/s:** First Choice
First Choice Plus

**Indications For Use:**

The First Choice and First Choice Plus 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 Milleson

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

510(k) Number K022076