K023997

MAR 0 3 2003

SECTION 5
SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared:	19th November 2002
Name of Device:	
Proprietary name:	TensCare Ultima NMS/EMS
Common name:	**For the TENS function** - TENS device **For the PMS/EMS function** – Powered Muscle Stimulator
Classification name:	**For TENS functions** Stimulator, Nerve, Transcutaneous, for Pain Relief - **84GZJ; 21 CFR 882.5890**. **For EMS functions** Powered Muscle Stimulator for re-education of muscles - **IPF; 21 CFR 890.5850**
Device Classification:	**For both TENS & EMS functions** - Class II
Predicate Device:	**For the TENS function** TensCare Ultima TENS – (K020846) **For the EMS function** TensCare XL-Y3 - (K011543)
Device Description:	**For the TENS function** A portable TENS device for pain relief. **For the EMS function** A portable EMS device for the re-education of muscles.
Intended Purpose/Use:	**For the TENS function**

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

For the EMS function

The Ultima NMS/EMS is indicated for:

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increasing range of motion

Technological Comparison:

The **Ultima NMS/EMS (the "New Device")** brings together **TENS** and **Powered Muscle Stimulator** functions from two previously cleared for market devices; namely the **Ultima TENS (K020846)** for the TENS functions and the **TensCare XL-Y3 (K011543)** for the Powered Muscle Stimulator functions.

The electrical, EMC and software technologies used in the **Ultima NMS/EMS (the 'New Device'),** are identical to the **Ultima TENS (the Predicate device – (K020846),** in that the same CPU series is utilised (the difference being that the variant used has increased memory capacity).

In addition, **the "New Device"** uses the same passive and active electrical components and PCB layout, as the **Predicate devices.**

The Powered Muscle Stimulator functions are derived from software programmed into the CPU device and are based on and virtually identical to the **Predicate device.**

Important anti-Misuse feature:

The TensCare Ultima NMS/EMS has a **Doctor Lock facility,** which means that at the **Treating Physician's discretion,** the patient has no

	control over the devices outputs; the Programs are pre-set by the **Treating Physician.** • The use of **'shrouded patient cable connectors'** to comply with FDA's Final Rule "Medical Devices: Establishment of Performance Standards for Electrode Lead Wires and Patient Cables" is utilised to further ensure no hazards exist.
Labelling Comparison:	The Labelling is substantially equivalent to that of the predicate devices.
Non-Clinical Testing:	The results of Bench Testing demonstrate that the output characteristics of the TensCare Ultima NMS/EMS are substantially equivalent to those of the two predicate devices.
Clinical Testing:	Clinical Testing was not necessary as no new or innovative aspects have been introduced.
Safety of the Combination functions:	The TensCare Ultima NMS/EMS combines the functions of a TENS device and an EMS (Electrical Muscle Stimulator) or Powered Muscle Stimulator, into one package. Bench Testing, VVT and Risk Analysis, including FMEA, demonstrate that the device performs as intended, with no harm to the User. Also, it is not possible to use the TENS and the EMS functions simultaneously. Mechanical integrity ensures that only one function can be selected at any one time.
Further safety information:	The "TensCare Ultima NMS/EMS" device has been on the European Market for the past two

years, in it's TENS form. During this time a review of Customer Complaints, Returned Product and the results of Post Market Feedback, has demonstrated that the product has performed as Intended, to it's Specified Requirements. The data analysed is summarised in this submission and the full data is available upon request. The Certificate of authority to CE Mark the "TensCare Ultima in accordance with the Medical Device Directive 93/42/EEC is included in Section 12 of this submission.

Conclusions:

The TensCare Ultima NMS/EMS is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 3 2003

TensCare Ltd.
C/O: Mr. Bernard Tremaine
Medical Device & QA Consultancy
76, Stockport Road
Timperley, Chesire
WA15 7SN. UK

Re: K023997
Dated: November 29, 2002
Received: December 3, 2002

Trade/Device Name: TensCare Ultima NMS/EMS Model XL-A3
Regulation Numbers: 21 CFR 890.5850 and 21 CFR 882.5890
Regulation Names: Powered muscle stimulator and Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Codes: IPF, GZJ

Dear Mr. Tremaine:

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-. 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,

Miriam C. Provost

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

SECTION 2
GENERAL INFORMATION

INTENDED USE / PURPOSE STATEMENT

TensCare Ultima NMS/EMS

For the TENS function

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

and;

For the EMS function

The Ultima NMS/EMS is indicated for the following;

- Relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Prevention of venous thrombosis of the calf muscles immediately after surgery
- Maintaining or increasing range of motion

Miriam C. Provost

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

510(k) Number K023997