MAY 21 2002

K020846

SECTION 5
SUMMARY OF SAFETY AND EFFECTIVENESS

Date Summary Prepared:	12th March 2002
Name of Device:	
Proprietary name:	TensCare Ultima
Common name:	TENS device
Classification name:	Stimulator, Nerve, Transcutaneous, for Pain Relief - **84GZJ; 21 CFR 882.5890**.
Device Classification:	Class II
Predicate Device:	FDTENS 2010 K994266
Device Description:	A portable TENS device for pain relief.
Intended Purpose/Use:	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.
Technological Comparison:	The TensCare Ultima XL-A1 has basic technological characteristics that are substantially equivalent to the predicate device. The same Microprocessor is used to control all functions and the use of pre-set output energy levels selectable by depression of a Button (as opposed to rotational control knobs on the predicate devices) is the same on both units. The electronic circuitry is virtually identical. and 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", applies to both units.

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Labelling Comparison:	The Labelling is substantially equivalent to that of the predicate device.
Non-Clinical Testing:	The results of Bench Testing demonstrate that the output characteristics of the TensCare Ultima 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.
Further safety information:	The TensCare "Ultima XL- A1" device has been on the European Market for the past 5 months. 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.
Conclusions:	The TensCare "Ulitima XL-A1" is substantially equivalent to the predicate device 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

MAY 21 2002

TensCare Ltd.
C/O Bernard J. Tremaine
Medical Device & QA Consultancy
76, Stockport Road
Timperley, Cheshire
WA15 7SN United Kingdom

Re: K020846
Trade/Device Name: Ultima TENS Model XL-A1
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: March 12, 2002
Received: March 15, 2002

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) 594-4659. 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,

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

Ultima Tens XL-A1

"For the symptomatic relief of chronic intractable pain"

Miriam C. Provost

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

510(k) Number K020846