JUL 3 0 2002

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K021436

1. **Submitter's Identification:**

Theratech, Inc.
1109 Myatt Blvd
Madison, TN 37115

Date Summary Prepared:

Contact: Ms. Tammy McGarr

2. **Name of the Device:**

Ttech Model 200E + TENS Device

3. **Predicate Device Information:**

K# 002874/S002, Well-TENS, Model WL-2103A, Well-Life Healthcare Inc.

4. **Device Description:**

The Ttech 200E + TENS Device is a battery-operated device that includes controllable output channels. This TENS device creates electrical impulses whose intensity, duration, number per second and modulation can be altered with the controls and switches. There are two separate amplitude controls (channels). Every channel can be connected with the lead wire, on which two pieces of electrodes are to be connected to the end of the wire to provide stimulation for the intended part of the body.

There are three operation modes:

- Convention Mode (c)
- Burst Mode (b)
- Modulated Mode (c)

The operator may choose any one of them, as applicable.

The device includes the following:

- 1 TENS Unit
- 2 Leads
- 1 9v Battery
- 1 Operation Manual
- 1 Carrying Case

5. **Intended Use:**

The Ttech 200E + TENS Device is intended for symptomatic relief of chronic intractable pain.

Please refer to our "Indications for Use" statement which is attached as Exhibit B.

6. **Comparison to Predicate Devices:**

The Ttech Model 200E+ is identical in all parameters, materials, processes, etc. to the Well-TENS Model WL-2103A device (K# 002874).

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

All required sections of the FDA "Guidance for TENS Devices" were met. All required IEC 60601-1 and IEC 60601-1-2 testing was met.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. **Conclusions:**

The Ttech Model 200E + TENS Device is identical to the predicate device with no new safety or effectiveness issues raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2002

Theratech, Inc.
MDI Consultants, Inc.
c/o Susan D. Goldstein-Falk
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K021436
Trade Name: Ttech Model 200 E + TENS Device
Regulation Number: 882.5890
Regulation Name: Transcutaneous electrical muscle stimulator
Regulatory Class: II
Product Code: GZJ
Dated: May 2, 2002
Received: May 9, 2002

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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,

for Mark N Melkerson

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

Exhibit B

510(k) Number (if known): K021436

Device Name: Ttech Model 200E + TENS Device

Indications For Use:

The Ttech Model 200E + TENS Device is intended for symptomatic relief of chronic intractable pain.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K021436

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)