Theratech, Inc.

510(K) SUMMARY

K024100

This summary of 510(k) 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: _____.

FEB 2 5 2003

1. Submitter's Identifications:
   Theratech, Inc.
   1109 Myatt Blvd, Madison, TN 37115

   Contact: Mr. Mike Price

   Date of Summary Preparation: September, 2002.

2. Name of the Device:

   IF series True sine interferential stimulator / Model: WL-2206, Well IF, Life IF and the customer private brand.

3. Information of the 510(k) Cleared Device (Predicate Device):

   IF-400 (k930535) and IF-4000 (k952683).

4. Device Description:

   The WL-2206 is the device which generates the small real-sine pulses of electrical current. The generated current may be delivered to the patient skin and/or underlying nerves through the cable and electrode placed on skin. Through the current stimulation the chronic and/or acute pain is to be relieved.

5. Intended Use:

   The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

   In addition, the standard format for the statement of indications and contraindication for use are provided hereafter.

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6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

   Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement.

   In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

   The true sine interferential stimulator, model WL-2206, has the same intended use and technological characteristics as the cleared device of IF-400 (k930536), and IF-4000 (k952683). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

   In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2003

Tony C.S. Chang
Wincet Consultant Co., Ltd.
No. 5, Alley 5, Lane Cheng Hsing
Chung Ching Rd., Pei Tun District
Taichung, Taiwan, R.O.C.

Re: K024100
Trade/Device Name: IF series True sine interferential stimulator models: WL-2206, Well IF, and Life IF
Regulation Number: Unclassified
Regulation Name: Interferential Stimulator
Regulatory Class: Unclassified
Product Code: LIH
Dated: December 6, 2002
Received: December 12, 2002

Dear Mr. Chang:

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,

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

Theratech, Inc.

510(K) SUMMARY

510(k) Number (if known):_____

Device Name: IF series True sine interferential stimulator / Model: WL-2206, Well IF, Life IF and the customer private brand.

Indications For Use:

The device is an interferential stimulator with TENS indications used for symptomatic relief and management of chronic intractable pain.

for Mark N. Milkerson

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

510(k) Number K024100

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Optional Format 1-2-96)