NOV - 9 1999

EXHIBIT #1

510(K) SUMMARY

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: K992209

1. **Submitter's Identification:**

   138 Medical Supplies Inc.
   313 Butler Street
   Brooklyn, NY 11217

   Date Summary Prepared:

   August 9, 1999
   Contact: Ms. Isabelle Liang

2. **Name of the Device:**

   1818 TENS Unit

3. **Predicate Device Information:**

   The 1818 TENS Unit is substantially equivalent to the Diamond Medical TX-3 TENS Unit, K#883188.

4. **Device Description:**

   The device is used to transmit electrical pulses through the skin to the underlying peripheral nerves to help in the blockage of the pain signal traveling to the brain.

5. **Intended Use:**

   This TENS device is indicated for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post surgical and post traumatic acute pain problems.

K992709

6. **Comparison to Predicate Devices:**

The 1818 TENS Unit is substantially equivalent to the Diamond Medical TX-3 TENS Unit.

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

All required sections of the AAMI/ANSI NS-4 Standard 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 1818 TENS Unit has the same intended use and technological characteristics as the TX-3 TENS Unit device. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that technological characteristics do not raise any new questions of safety or effectiveness. Thus, the 1818 TENS Unit is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 1999

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

Re: K992709
Trade Name: 1818 TENS Unit
Regulatory Class: II
Product Code: GZJ
Dated: August 9, 1999
Received: August 11, 1999

Dear Ms. Goldstein-Falk:

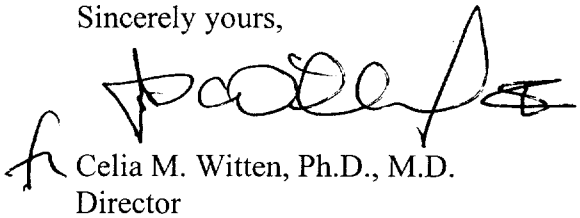
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

This letter will allow you to begin marketing your device as described in your 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.

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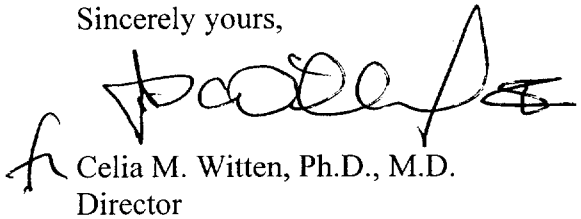
Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K992709

DEVICE NAME: 138 Medical Supplies Inc. 1818 TENS Unit

INDICATIONS FOR USE:

This TENS device is indicated for the symptomatic relief and management of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post surgical and post traumatic acute pain problems.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992709