



SEP 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Keith J. Geolat
Manager of Quality Assurance and Regulatory Affairs
Uni-Pateh Medical Supplies
Post Office. Box 271
1313 West Grant Boulevard
Wabasha, Minnesota 55981

Re: K983097
Trade Name: TENS/FES/NMES Electrodes
Regulatory Class: II
Product Code: GXY
Dated: June 16, 1999
Received: June 22, 1999

Dear Mr. Geolat:

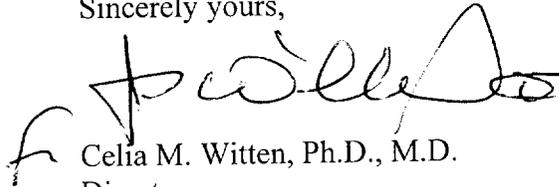
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4659. 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" (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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

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): K962332

Device Name: TENS / FES / NMES Electrodes

Indications For Use:

To conduct electrical stimulation to a patient's skin.

Single patient use.

Repositionable, self-adhering.

Over the counter use.

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

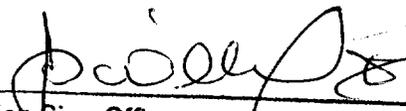
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)


(Division Sign-Off)

Division of **General Restorative Devices** K983097
510(k) Number _____

3

September 9, 1999

510(k) Summary

1) Establishment Address, Contact, and Registration Number:

Uni-Patch
1313 West Grant Blvd.
Wabasha, MN 55981

Registration Number: 2183164

Contact: Keith Geolat – Manager of Quality Assurance & Regulatory Affairs
Phone: (651) 565-2601

2) Device Name

A. Classification: Electrode, Cutaneous, Classification Number: 84 GXY
Class II

B. Common/Usual: TENS, FES, NMES Stimulating Electrodes

3) Substantial Equivalence

The Uni-Patch TENS, FES, and NMES Electrodes with conductive gel are substantially equivalent to electrodes that have already been found to be substantially equivalent through the 510(k) premarket notification process. Uni-Patch currently manufactures and distributes the following electrodes carrying the same indication for use.

Tantone Multi-Day 633 TENS Electrode – K871222

Reusable TENS Paravertebral Pad 641 Back Electrode – K901575A

Uni-Patch proposes to manufacture and market this electrode family with conductive gel using similar designs and compositions of previously approved devices.

4) Device Description

The device provides a means for establishing electrical contact between the lead connected to a TENS, FES, or NMES stimulation device and the skin. The device consists of conductive hydrogel, a conductive lead wire, a non-conductive cloth backing material with a printed conductor on the side contacting the hydrogel.

5) Intended Use

The electrode is used in conjunction with electrical stimulating therapy for the symptomatic relief and management of chronic pain or some types of acute pain, muscle stimulation therapy for the relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, and maintaining or increasing range of motion.

6) Technological Characteristics Comparison

Uni-Patch has compared our electrode to other legally marketed electrodes that carry the TENS and NMES indication; the Medtronic ComfortEase (K851303), and the 3M Myocare (K905539) Muscle Stimulation Electrodes.

There are no published performance standards for TENS, FES, or NMES electrodes, so Uni-Patch used impedance levels as the criteria for effectiveness testing. When measuring the electrode impedance, driven at 1K-Hz, we have determined that the electrode impedance values were comparable to all the legally marketed electrodes identified above. (See attached data.)

Additionally, the Hydrogel used in the Uni-Patch electrodes has passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance for Medical Devices. The Hydrogel used in Uni-Patch's electrodes has been used extensively throughout the industry for over fifteen years.

Based on this testing Uni-Patch considers its TENS, FES, NMES stimulating electrodes to be as safe and effective as the Medtronic ComfortEase and the 3M Myocare Muscle Stimulation electrodes.