10. 510(k) Summary

MEDIPOINT, MICROCURRENT THERAPY

Contact: Larry Ratliff
Medipoint USA
Pocatella, Idaho 83204

Tel: (208) 232-2941

Sponsor: Medipoint Ltd.
12 Wolfe Close
Parkgate Business Park, Knutsford
Chesire, WA16 8XJ, UK

Tel: 01565 632000

K982961

10. 1. Device Name

MEDIPOINT is provided as follows:

a. Trade Name - MEDIPOINT

b. Common Name – Microcurrent Therapy

c. Classification Name

- 21 CFR Sec. 882.5890 Transcutaneous electrical nerve stimulator for pain relief

10. 2. Predicate Device / Company Names and Addresses

The predicate device is listed below with its 510(k) clearance number.

SOLITENS™	K(913522)	INNOVATIVE DESIGNER PRODUCTS, INC. Saul Liss 175 Rock Road Glen Rock, NJ 07452

10. 3. Description of Device

MEDIPOINT is a portable hand held battery operated micro current pulse generator [redacted] using a very minute biphasic DC current.

10. 4. Intended Use

MEDIPOINT is intended for relief of chronic or acute pain.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 1999

Jules T. Mitchel, Ph.D.
Target Health Inc.
Representing Medipoint Limited
310 Madison Avenue, 22nd Floor
New York, New York 10017

Re: K982961
Trade Name: Medipoint
Regulatory Class: II
Product Code: GZJ
Dated: March 9, 1999
Received: March 10, 1999

Dear Dr. Mitchel:

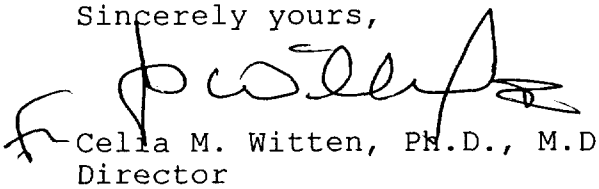
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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

510(k) Number (if known): K982961

Device Name: Medipoint

Indications For Use:

MEDIPOINT is an electronic pulse generator that has been designed to provide symptomatic relief of chronic intractable pain and post-traumatic acute pain (TENS).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982961

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)