K033358

NOV 1 4 2003

8.0 Chronic Pain Suppressor CPS-2000 510(k) Summary
(as required by section 807.92(c))

Submitter's Name: SurgiTech, Inc.
2424 Vista Way, Suite 300
Oceanside, CA 92054

Contact Person: Chris Crowell
Phone: (760) 450-0194
Fax: (760) 721-4290

Date Prepared: October 10, 2003

Trade or Proprietary Name: Chronic Pain Suppressor

Common or Usual Name: Interferential Current Therapy

SurgiTech Model Number: CPS-2000

Establishment Registration Number: 2032724

Device Class: II

Classification Name: Interferential Current Therapy

CFR #: Unclassified

Product Code: LIH

Description of Device:
The Chronic Pain Suppressor CPS-2000 is a rechargeable battery operated Interferential Current Therapy device that utilizes an output circuit to generate a symmetric monophasic sine or square waveform of electrical current. Delivered along a patient cable and lead wires to electrodes placed on the skin. The physician prescribed and programmed output passes through the skin and actives the underlying nerves. The symptomatic relief from chronic intractable pain can be obtained from this electrical stimulation.

Intended Use:
The intended uses of the Chronic Pain Suppressor are:

- Symptomatic relief of chronic intractable pain
- Adjunctive treatment for the management of post-traumatic or post-surgical pain

Predicate Device Information:

Device	Applicant	510(k) #
SD-730	Skylark Device	K992652
HMP 4000	HMP 4000, Inc.	K924961

Substantial Equivalence:
The Chronic Pain Suppressor CPS-2000 is equivalent in basic form and function to almost any other Class II Interferential Current Therapy device. A difference to the legally marketed predicate devices is the "Patient-Lock" feature. This difference in no way affects the safety or effectiveness of the device. Ultimately, the safety is raised as the prescribed treatment parameters programmed by the physician are protected from alteration. The patient may only initiate and stop treatment at designated time intervals, adjust the intensity, and view the session countdown timer for the next treatment.

Performance Data:
The descriptive characteristics presented are thorough enough to ensure the substantial equivalence of the Chronic Pain Suppressor CPS-2000 to the legally marketed predicate devices. The descriptive characteristics include the data provided in the Substantial Equivalence Comparison Table within this premarket notification submission.

Conformance to Voluntary Standards:

- UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- AAMI/ANSI NS4:1986/(R)2002 Transcutaneous Electrical Nerve Stimulators – specifically items 3.1-3.1.2.1, 3.1.3-3.2.5, 4.1-4.2.3.2

Conclusion:
The Chronic Pain Suppressor CPS-2000 is as safe and effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Mr. Christopher Crowell
Quality Assurance Manager
SurgiTech, Inc.
2424 Vista Way, Suite 300
Oceanside, California 92054

Re: K033358
Trade/Device Name: Chronic Pain Suppressor CPS-2000
Regulatory Class: Unclassified
Product Code: LIH
Dated: October 10, 2003
Received: October 20, 2003

Dear Mr. Crowell:

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.

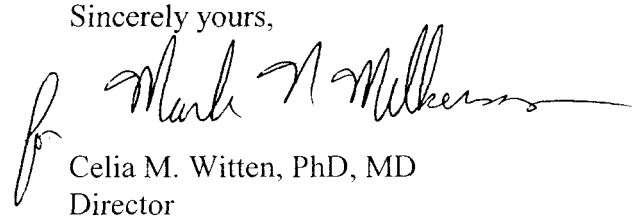
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K033358

Device Name: Chronic Pain Suppressor CPS-2000

Indications for Use:

- Symptomatic relief of chronic intractable pain.
- Adjunctive treatment for the management of post-traumatic or post-surgical pain.

(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
and Neurological Devices

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(Optional Format 3-10-98)