MAY 1 1998

K980393

510(k) SUMMARY

Submitter Information (21 CFR 807.92(a)(1))

Submitter: FemRx, Inc.
1221 Innsbruck Drive
Sunnyvale, CA 94089

Contact: Ms. Jean La Douceur
Vice President Product Assurance
(408) 752-8580 x 104

Summary Date: January 30, 1998

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): Soprano™

Name (usual): Cryo-Therapy System

Classification: Class II, 21 CFR 878.4350, "cyrosurgical unit and accessories"

Predicate Device (21 CFR 807.92 (a)(3))

The Cryo-Therapy System (Soprano™) is substantially equivalent to the Frigitonics CCS 100 and CMS AccuProbe in terms of intended use, principle of operation, and control function.

Description of Device (21 CFR 807.92 (a)(4))

The FemRx Soprano Cryo-Therapy System is designed to be a general use cryotherapy system for the destruction or cryoablation of tissue. The system allows the circulation of a cryo-refrigerant from the console to the reusable cryoprobe.

Intended Use (21 CFR 807.92 (a)(5))

The Soprano™ Cryo-Therapy System is intended for use in the surgical ablation of tissue by the application of extreme cold in the fields of dermatology, general surgery, neurosurgery, thoracic surgery, E.N.T., gynecology, oncology, proctology and urology.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The results from the nonclinical tests indicate the Cryo-Therapy System is equivalent to the predicate devices in terms of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1998

George Savage, M.D.
Chief Medical Officer
FemRx Incorporated
1221 Innsbruck Drive
Sunnyvale, California 94089

Re: K980393
Trade Name: Soprano Cyro-Therapy System
Regulatory Class: II
Product Code: GEI
Dated: January 30, 1998
Received: February 2, 1998

Dear Dr. Savage:

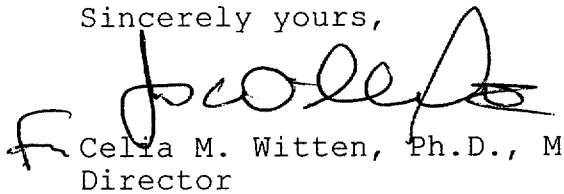
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

INDICATIONS FOR USE

510(K) Number (if known) K980393

Device Name: Cryosurgical Unit and Accessories

Indications for Use:

The Soprano™ Cryo-Therapy System is intended for use in the surgical ablation of tissue by the application of extreme cold in the fields of dermatology, general surgery, neurosurgery, thoracic surgery, E.N.T., gynecology, oncology, proctology and urology.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980393