K971305

510(k) SUMMARY

AUG 1 1 1997

The FemRx Focused Monopolar (FMP) OPERASTAR™ System [with Dispersive Electrode Option] is identical to FemRx's currently cleared FMP OPERASTAR™ System with the exception that it includes the option of using a standard dispersive skin electrode. When used in this way it is basically identical to our original OPERASTAR™ System except that it incorporates a PEARL electrode (Physiologic endometrial ablation / resection loop). This loop is partially insulated to "focus" the current toward the tissue and avoid the reduction in effect associated with conventional devices. The use of isotonic solutions (e.g., NaCl or Ringers Lactate) is strongly recommended in order to reduce the risks associated with fluid overload.

The FMP OPERASTAR System differs from currently marketed bi-polar devices in that it continues to have a single active electrode (wire loop or Star loop) as opposed to two active electrodes. The return electrode (the metallic outer Morcellator housing of the device OR a standard dispersive pad located on the patients skin) has such a large surface area relative to the active electrode that there can be no tissue coagulating (much less cutting or ablating) effect at its surface.

In vitro extirpated uteri studies comparing the resection and ablation performance of the Focused Monopolar device with the predicates confirm that tissue effects are substantially equivalent to currently marketed devices. In addition, clinical testing has demonstrated equivalent performance between the FMP OPERASTAR™ System (recently cleared via K964441) and the FMP OPERASTAR™ System [with Dispersive Electrode Option].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

George M. Savage, M.D.
Senior Vice President
FemRx
1221 Innsbruck Drive
Sunnyvale, California 94089

AUG 11 1997

Re: K971305
Focused Monopolar (FMP) OPERASTAR™ System
with Dispersive Electrode Option
Dated: July 3, 1997
Received: July 11, 1997
Regulatory class: II
21 CFR §884.4160 and §884.1690
Product code: 85 HIH & KNF

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971305

Device Name: FemRx™ FMP OPERASTAR™ (with Dispersive Electrode Option)

Indications For Use:

The FemRx™ Focused Monopolar (FMP) OPERASTAR™ System is intended for gynecologic hysteroscopic / electro-surgical use by trained professional gynecologists in hospital or office environments. It is used to resect and / or ablate endometrial tissue.

INDICATIONS:	CONTRAINDICATIONS:
Abnormal Uterine Bleeding	Pregnancy
Submucous Fibroids	Pelvic Infection
Endometrial Polyps	Cervical Malignancy
	Previously diagnosed Endometrial cancer

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971305

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

(Optional Format 1-2-96)

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