OCT 5 1999

K992714

SECTION 15

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Submitter: HysteRx, Inc.
32236-E Paseo Adelanto
San Juan Capistrano, CA 92675 USA
(949) 488-8701

b. Contact Person: Judy F. Gordon, D.V.M.
Official Correspondent for HysteRx, Inc.
(949) 854-6314

c. Date Summary Prepared: August 10, 1999

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: MicroGRASP Monopolar Coagulator

b. Classification Name: Electrosurgical cutting and coagulation device

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company: Microsurge, Inc.

Device: Microsurge Front-End Grasping Devices

510(k) : K922802

Date Cleared: January 29, 1993

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The MicroGRASP Monopolar Coagulator is an instrument designed for grasping and coagulation of soft tissue and blood vessels during surgical procedures. The MicroGRASP Monopolar Coagulator contains materials similar to those used in the predicate device, is of similar design and has the same operating principle as the predicate device.

5. Statement of intended use:

The MicroGRASP Monopolar Coagulator is indicated for use in the grasping and coagulation of soft tissue and blood vessels up to 3 mm during open and guidance-assisted surgical procedures.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

A comparison of the technological characteristics of the device and its predicate is shown in the following table:

Comparative Technological Characteristics

CHARACTERISTICS	Microsurge Front-End Grasping Devices	MicroGRASP Monopolar Coagulator
Intended Use	To remove tissue or control bleeding during general surgical endoscopic or laparoscopic procedures	For grasping and coagulation of soft tissue and blood vessels up to 3 mm during open and guidance-assisted surgical procedures
Operating Principle	Electrosurgical handpiece for coagulation; electro-cautery	Electrosurgical handpiece for coagulation
Bipolar/Monopolar	Monopolar	Monopolar
Bench Testing	ANSI/AAMI HF-18/1986	ANSI/AAMI HF-18/1993
Handpiece Configuration(s)	Scissor-type handpiece	Articulating jaws design, with 2 or 4 jaw grasper, or blunt electrode
Materials: **Handle** **Inner shaft** **Outer shaft** **Tips** **Connector**	 Plastic, with stainless steel pin, washer, and spring Stainless steel Teflon sheath (implant grade) Stainless steel (implant grade) Nickel plated brass	 Plastic, with stainless steel pins and gears Stainless steel Nylon 11 sheath (implant grade – USP Class VI) Stainless steel (implant grade) Nickel plated brass
Disposable/Reusable	Single use, disposable	Single use, disposable

7. Brief summary of nonclinical tests and results:

The MicroGRASP Monopolar Coagulator has been designed and tested to applicable standards (ANSI/AAMI HF-18/1993). The MicroGRASP Monopolar Coagulator does not raise any new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1999

HysteRx, Inc.
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services
18732 Saginaw
Irvine, California 92612

Re: K992714
Trade Name: MicroGRASP Monopolar Coagulator
Regulatory Class: II
Product Code: GEI
Dated: August 10, 1999
Received: August 12, 1999

Dear Dr. Gordon:

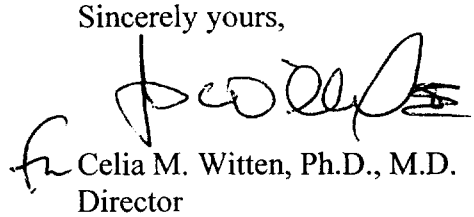
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Page___of___

510(k) Number (if known): K992714

Device Name:_____

Indications For Use:

The MicroGRASP Monopolar Coagulator is indicated for use in the grasping and coagulation of soft tissue and blood vessels up to 3 mm during open and guidance-assisted surgical procedures.

(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 K992714

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

(Optional Format 1-2-96)