JUL 27 2007

MODERN MEDICAL EQUIPMENT MFG. LTD.
5F Gold King Ind. Bldg., - Tai Lin Pai Rd., - KwaiChung, Hong Kong

Modern Medical Equipment
C/O E & M Engineering
1705 Dabney Road,
Richmond, Va. 23230

Tel : (804) 353 7160
Fax : 804 - 353 7161
21 June 2007

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporation Blvd.
Rockville, Maryland 20850

Re: 510(k) Premarket Notification, 510 K # 070877
Gyn LLETZ Electrode

Dear Sir or Madam,
RE: 510(k) Notification

This is to notify you that Modern Medical intends to manufacture the following device and market it in the United States.

The following information and the attached technical information are provided in accordance with 21CFR 807.87

a. Device Name

Classification Name:	Gyn LLETZ Electrode
Common/ Usual name:	LOOP Electrode
Proprietary Name:	Endocervical Electrode / EZ hysterectomy Electrode

b. Establishment Registration

Owner Operator number	9005334
Registration number:	9680721
Establishment Name,	Modern Medical Equipment C/O E & M Engineering 1705 Dabney Road, Richmond, Va. 23230

Telephone: (804) 353 7160
Fax: (804)353 7161
Email address: bstillman@enmengineering.com

c. Classification Information
Classification and Review Panel: Obstetrics/Gynecology

Class: II

Product Code **HGI**

d. Performance Standards or Special Controls

Meet the electrical and mechanical requirements of ANSI/AAMI HF-18 Standard for Electrosurgical Devices.

e. Labeling

Copies of draft labeling for this device is attached

f. Rationale for Substantial Equivalence

The subject device is substantially equivalent to the predicate device.

Company	Device	K number
Apple Medical	Fisher Cone Biopsy Electrode	K061651

A discussion regarding the reason and basis for substantial equivalence of the device to the legally marketed predicate device is attached, "Substantial Equivalence to Predicate Devices".

In accordance with the Safe Medical Devices Act of 1990 (SMDA), the safety and effectiveness information upon which this substantial equivalence determination is based will be made available by Modern Medical to interested persons upon request.

To the best of my knowledge, the information and date submitted herein is truthful and accurate. If you require any additional information or clarification, please contact me.

Sincerely,

Bob Stillman
Modern Medical Equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 27 2007

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Modern Medical Equipment
% Mr. Bob Stillman
Official Correspond
E & M Engineering, Inc.
1705 Dabney Road
RICHMOND VA 23230

Re: K070877
Trade/Device Name: Endocervical Hysterectomy Electrode
Regulation Number: 21 CFR 884.4120
Regulation Name: Gynecologic electrocautery and accessories
Regulatory Class: II
Product Code: HGI
Dated: July 13, 2007
Received: July 16, 2007

Dear Mr. Stillman:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

U.S. Food and Drug Administration

Center for Devices and Radiologic Health

Indications for Use

510K number (if known) : **K070877**
Device Name : **Endocervical Hysterectomy Electrode**

Indications for Use

A. **Endocervical Hysterectomy Electrode** is indicated for treatment of following Condition

1. **Excision of inner cervix during supracervical hysterectomy.**

Prescription Use ✓ AND/OR Over-The counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office device evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070877