

MAY 1 1998

510(k) Summary
Imagyn Medical Technologies, Inc.
Optical Aspirating Curette (OAC)

K980096

P192

I. General Information on Submitter:

Name: Imagyn Medical Technologies, Inc.
Address: 5 Civic Plaza, Suite 100
Newport Beach, CA 92660
Phone: (714) 362-2500
Fax: (714) 362-2520

Name of Contact Person: Ronald H. Bergeson
Date Summary Prepared: January 8, 1998

II. General Information on Device

Name: Optical Aspirating Curette

Classification Name:

Obstetric-gynecologic general manual instrument, uterine curette (curette
portion of device), 21 C.F.R. § 884.1175

Hysteroscope and accessories (hysteroscope portion of device), 21 C.F.R. §884.1690

III. Predicate Devices:

The flexible fiberoptic hysteroscope component is similar to the MicroSpan Hysteroscope (510(k) No. K961688).

The disposable curette component is similar to the Milex "Tis-U-Trap" Uterine Suction Curette, Milex, (510(k) No. K760264); and the Pipelle "Endometrial Suction Curette", (510(k) No. K881456).

IV. Description of the Device:

Imagyn's Optical Aspirating Curette consists of a disposable aspirating curette intended to remove tissue from the uterus and from the mucosal lining of the uterus by scraping and aspirating. The curette has a multi-lumen design that accommodates the introduction of Imagyn's reusable fiberoptic hysteroscope, which allows for visualization of the uterine cavity during the curettage procedure.

V. Intended Use:

The Optical Aspirating Curette is indicated for use in visualizing the interior of the uterus and obtaining an endometrial tissue sample adequate for histological evaluation.

VI. Technological Characteristics of Device Compared to Predicate Device:

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The OAC uses the same type of curette as the Milex "Tis-U-Trap" curette device, and the same type hysteroscope as the Imagyn "MicroSpan" Hysteroscope device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Ronald H. Bergeson
Corporate Director, Regulatory Affairs
IMAGYN Medical Technologies, Inc.
27651 La Paz Road
Laguna Niguel, CA 92677

Re: K980096
Optical Aspirating Curette
Dated: March 13, 1998
Received: March 16, 1998
Regulatory Class: II
21 CFR §884.4530/Procode: 85 HCY
21 CFR §884.1690/Procode: 85 HIH

Dear Mr. Bergeson:

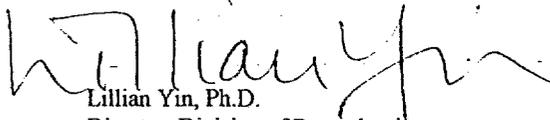
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

INDICATION FOR USE FORM

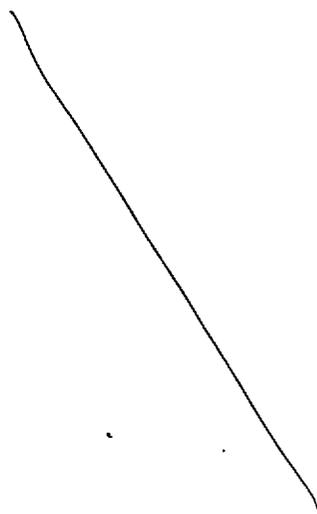
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510 (k) Number (if known): K980096

Device Name: Optical Aspirating Curette

Indications for Use:

The Optical Aspirating Curette is indicated for use in visualizing the interior of the uterus and obtaining an endometrial tissue sample adequate for histological evaluation.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Sattley
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980096

Prescription Use
(Per 21 CFR 801.1091)

OR

Over-The-Counter Use

(Optional Format 1-2-96)