K972426
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Imagyn

SEP 23 1997

510(k) Summary

Submitter:	Imagyn Medical, Inc. 27651 La Paz Road Laguna Niguel, CA 92677-3917 (714) 362-2500 Contact: Debra A. Rinderer
Summary Preparation:	June 25, 1997
Device:	MicroSpan Gold Hysteroscope and MicroSpan Hysteroscope Sheath
Predicate Devices:	Imagyn MicroSpan Hysteroscope Imagyn MicroLap-Gold Laparoscope Optimed Technologies Rigid Fiber Optic Hysteroscope
Device Description:	The MicroSpan-Gold Hysteroscope is a small diameter, rigid, fiberoptic hysteroscope without through lumens. The device consists of an outer stainless steel shaft, inner illumination fibers, and an imaging fiber bundle. At one end of the imaging bundle is the distal lens and at the other is the rotatable eyepiece. An endoscopic light source is connected to the light post of the hysteroscope through compatible light cables. If desired, the eyepiece can be connected through a focusing optical coupler to a camera head which carries the image by cable to the camera. The MicroSpan Hysteroscope Sheath is offered with irrigation/insufflation and aspiration ports and an instrument channel. The device is provided sterile for single use, and is made from both metal and plastic components.
Intended Use of Device:	The MicroSpan Gold Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures. The MicrSpan Hysteroscope Sheath is indicated for use in providing access to the uterine cavity for the Imagyn Hysteroscope or other hysteroscopic instruments during diagnostic and operative hysteroscopic procedures.
Technological Comparisons:	Light from a high intensity light source (e.g. xenon) is transmitted through illumination fibers to the distal end of the hysteroscope in order to illuminate the target object. The distal lens system focuses the image of the object onto image fibers, which then transmits the image to the proximal lens system. The proximal lens system magnifies and focuses the image onto an eyepiece at the proximal end of the hysteroscope for viewing and/or directly to standard video cameras, monitors and recording equipment. The MicroSpan Gold Hysteroscope and the predicate devices all have equivalent technological characteristics.

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Technological Comparisons (continued)	The MicroSpan Hysteroscope Sheath is identical in all respects except maximum outer diameter to the previously cleared MicroSpan Hysteroscope Sheath. The device is designed to achieve hysteroscope and/or hysteroscopic instrument insertion without loss of uterine distention.
Performance Summary	Non-clinical tests were performed to demonstrate that the device performed according to its description. Testing included evaluation of optical and mechanical characteristics of the device and the effect of simulated reuses on these characteristics. The device was also evaluated for its electrical safety, thermal characteristics, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1997

Ms. Debra A. Rinderer
Regulatory Affairs Specialist
Imagyn Medical, Inc.
27651 La Paz Road
Laguna Niguel, California 92677

Re: K972426
MicroSpan Gold Hysteroscope and MicroSpan Hysteroscope Sheath
Dated: June 26, 1997
Received: June 27, 1997
Regulatory class: II
21 CFR §884.1690/Product code: 85 HIH

Dear Ms. Rinderer:

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,

William Yin

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

INDICATIONS FOR USE

510(k) Number (if known): K972426

Device Name: MicroSpan Gold Hysteroscope and MicroSpan Hysteroscope Sheath

Indications for Use:

The MicroSpan Gold Hysteroscope is used to permit viewing of the cervical canal and the uterine cavity for the purpose of performing diagnostic and surgical procedures.

The MicroSpan Hysteroscope Sheath is used to provide access to the uterine cavity for the MicroSpan Gold Hysteroscope or other hysteroscopic instruments during diagnostic and operative hysteroscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Tatting

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972426

Prescription Use ✓ OR Over-The-Counter Use ____