K092278

SEP 2 9 2009

510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
Gyrus ACMI® Invisio® Digital Hysteroscope System

General Information

Manufacturer:	Gyrus ACMI Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A. L. Baillie, MS Sr Regulatory Affairs Specialist Tel. # 508 804-2738 Fax # 508 804-2624
Date Prepared:	July 24, 2009

Device Description

Classification Name:	Hysteroscope and accessories (21CFR 886.1690), Class II Surgical camera and accessories, (21 CFR 878.4160), Class I
Trade Name:	Gyrus ACMI Invisio Digital Hysteroscope System
Generic/Common Name:	Endoscope, Video Camera and accessories Hysteroscope and accessories

Predicate Devices

ACMI DUR®-Digital Ureteroscope & Choledochoscope, (DUR-D)	K060269
Gyrus ACMI IPN-2505 Percutaneous Nephroscope	K072594
Karl Storz MVM 7.5French Flexible Hysteroscope	K990411
Olympus Visera HFY-V Hysterovideoscope	K022445

Intended Use

The Gyrus ACMI Invisio Digital Hysteroscope is intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

The Gyrus ACMI Invisio Digital Hysteroscope System includes the Invisio Digital Hysteroscope and IDC Invisio™ Controller. The IDC Controller is intended to be used to process the video signal from the Invisio Digital Hysteroscope and ensure brightness, image clarity and color.

Diagnostic Hysteroscopy:

- Abnormal uterine bleeding
- Infertility & pregnancy wastage

- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain

Operative Hysteroscopy:

- Directed biopsy
- Removal of fibroids and polyps
- Transection of intrauterine adhesions
- Transection intrauterine septa

Product Description

The Gyrus ACMI® Invisio® Digital Hysteroscope System is comprised of the Invisio Digital Hysteroscope and Invisio Digital Controller (IDC-1500). The Gyrus ACMI Invisio Digital Hysteroscope is a semi-rigid (rigi-flex) hysteroscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. There is a miniature CMOS sensor located in the distal tip, wiring running through the endoscope shaft, a printed circuit board (PCB), a light-emitting diode (LED) light source located in the handle, and an electrical cord that connects the endoscope to the Camera Control Unit (CCU). The Invisio Digital Hysteroscope connects to a CCU, (the Invisio Digital Controller (IDC-1500)), that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

Technological Characteristics and Substantial Equivalence

The Gyrus ACMI® Invisio® Digital Hysteroscope System, utilizes features included in the predicate Gyrus ACMI Invisio Digital, IPN-2505 Percutaneous Nephroscope K072594, and the ACMI DUR®-Digital Ureteroscope & Choledochoscope, DUR®-D K060269. The proposed device incorporates the same CMOS video imaging technology located in the endoscope as the aforementioned Invisio predicates. The subject Invisio Digital Hysteroscope System utilizes the same model Invisio Controller loaded with the same Invisio digital software. The internal shaft construction and flexible/articulating distal section contains similarly designed defection pulleys/wires, and electrical wiring as the predicate Invisio DUR®-D. The subject and two aforementioned Invisio predicates also incorporate similarly designed bifurcated fiber optic illumination bundles that carry/transmit light from the same design LEDs, located in the handles of each device, through the shaft to the distal tip. The subject hysteroscope and predicate DUR®-D also share the same patient contacting materials used in the distal tip, working channel and deflection cover.

Like other predicate hysteroscopes: the Karl Storz MVM 7.5 Fr Flexible Hysteroscope (K990411); and the Olympus Visera HFY-V Hysterovideoscope (K022445); the proposed hysteroscope has similar shaft diameter and working length and is intended for viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.

In summary, the Gyrus ACMI® Invisio® Digital Hysteroscope System is substantially equivalent to the four predicate devices and presents no new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 29 2009

Graham A. L. Baillie, MS
Sr. Regulatory Affairs Specialist
Gyrus ACMI, Inc.
136 Turnpike Road
SOUTHBOROUGH MA 01772-2104

Re: K092278
Trade/Device Name: Invisio Digital Hysteroscope System
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: July 24, 2009
Received: July 28, 2009

Dear Mr. Baillie:

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 (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K092278
Device Name: Invisio Digital Hysteroscope System

Indications for Use

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Prescription Use: __ X __ **OR** Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K092278