K090814

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

APR 20 2009

General Information

Manufacturer:	Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Graham A. L. Baillie, MS Senior Regulatory Affairs Specialist
Date Prepared:	Mar , 2009

Device Description

Classification Name:	Endoscope and accessories (21 CFR 876.1500), Class II Gastroenterology & Urology Panel Surgical camera and accessories General & Plastic surgery Panel (21 CFR 878.4160), Class I
Trade Name:	Gyrus ACMI® Invisio® ICN
Generic/Common Name:	Endoscope, Video Camera and accessories

Predicate Device

ACMI® Invisio® ICN CystoNephroscope System	K042225

Intended Uses

The Gyrus ACMI® Invisio® ICN Digital Flexible CystoNephroscope System (which includes the ICN scope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

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Product Description

Like the predicate ACMI® Invisio® ICN CystoNephroscope System, the Gyrus ACMI® Invisio® ICN is a flexible endoscope that incorporates CMOS (complimentary medical oxide semi-conductor) sensor technology to generate an image. The ICN can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney.

The ICN incorporates the same basic video imaging technology located in the endoscope as the predicate device. 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.

Like the predicate device, the ICN uses the same Camera Control Unit (CCU) that contains printed circuits boards (PCBs), software, power supply and power cables to process and display the images transmitted by the camera.

This Special 510(k) proposes video sensor performance modifications to the ACMI® Invisio® ICN. The indications for use, labeling, principles of operation, materials and overall dimensions of the proposed Gyrus ACMI® Invisio® ICN remain the same as in the predicate device.

Summary of Safety and Effectiveness

The proposed modifications for the Gyrus ACMI® Invisio® ICN, as described in this submission, are substantially equivalent to the predicate device. The proposed modification in design specifications, performance specifications, and software specifications are not substantial changes or modifications, and do not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 20 2009

Mr. Graham A. L. Baillie, MS
Senior Regulatory Affairs Specialist
Gyrus ACMI, Inc.
136 Turnpike Road
Southborough MA 01772

Re: K090814
Trade/Device Name: Gyrus ACMI® Invisio® ICN
Regulation Number: 21 CFR 876.5130
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: March 23, 2009
Received: March 25, 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.

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.

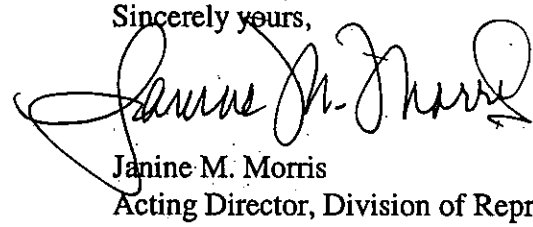
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.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). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,



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: K090814

Device Name: Gyrus ACMI® Invisio® ICN

Indications for Use:

The Gyrus ACMI® Invisio® ICN (CystoNephroscope) System (which includes the ICN Endoscope and Controller) is intended for use to examine body cavities, hollow organs and canals in the body, in the urinary tract, and can be used percutaneously to examine the interior of the kidney; and, using additional accessories, can be used to perform various diagnostic and therapeutic procedures.

Prescription Use: __ **X** __ (Per 21 CFR 801.109) AND/OR Over-the-Counter Use: _____ (21 CFR 801 Subpart C)

(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 K090814