

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

K072594
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Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope System

General Information

DEC 13 2007

Manufacturer: Gyrus ACMI, Inc.
136 Turnpike Rd.
Southborough, MA 01772-2104

Contact Person: Graham A.L. Baillie
Senior Regulatory Specialist
Tel. #: 508-804-2738
Fax #: 508-804-2624

Date Prepared: September 10, 2007

Device Description

Classification Name: Endoscope and accessories
(21 CFR 876.1500), Class II
Surgical camera and accessories
(21 CFR 878.4160), Class I

Trade Name: **Gyrus ACMI® IPN-2505, Invisio®
Smith™ Percutaneous Nephroscope
System**

Generic/Common Name: Endoscope, Video Camera and accessories

Predicate Devices

ACMI® DUR-Digital Ureteroscope and Choledochoscope System	K060269
ACMI® MRO™ -20 Rigid Percutaneous Nephroscopes	K791182
ACMI® MR-6A/MR-6LA Autoclavable Ureteroscopes	K052044

Intended Uses

The **Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope System** (which includes the IPN-2505 Invisio® Smith™ Percutaneous Nephroscope and IDC-1500 Invisio® Camera Control Unit) is intended for close visualization of

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the urinary bladder, renal pelvis and major calyces. The IPN-2505 can be introduced through a percutaneous tract into the kidney and can also be introduced through the urethra to access the bladder. Additional accessories can be used to perform various diagnostic and therapeutic procedures.

Product Description

The Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope (referred to hereafter as the IPN-2505) is a rigid endoscope that incorporates CMOS (complimentary metal 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 IDC-1500 Camera Control Unit (CCU).

The IPN-2505 can be introduced either through the urethra into the bladder or through a percutaneous tract into the abdominal cavity or kidney. The IPN-2505 uses an IDC-1500 CCU 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 IPN-2505, utilizes features incorporated into the following legally marketed predicate devices:

The IPN-2505 incorporates the same basic CMOS video imaging technology located in the endoscope as the predicate ACMI® DUR-Digital Ureterscope and Choledochoscope System (K060269).

The IPN-2505 shaft is dimensionally similar to its predicate ACMI® MRO-20 Rigid Percutaneous Nephroscope (K791182), having the same working channel diameter, similar lengths and diameters. The IPN-2505 utilizes similar materials in its construction as the predicate MRO-20 (K791182) and the predicate MR-6A/MR-6LA Autoclavable Ureterscope (K052044).

Like the predicate MRO-20 the IPN-2505 is indicated to allow close visualization of the renal pelvis and major calyces through a percutaneous tract.

In summary, the Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope System is substantially equivalent to the predicate devices and presents no new questions of safety or efficacy.



DEC 13 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K072594
Trade/Device Name: **Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope System**
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FGA, FEC and FED
Dated: September 12, 2007
Received: September 14, 2007

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 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 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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope System

510(k) Number: *K072594*

Intended Use:

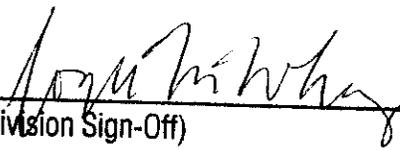
The Gyrus ACMI® IPN-2505, Invisio® Smith™ Percutaneous Nephroscope System (which includes the IPN-2505 Invisio® Smith™ Percutaneous Nephroscope and IDC-1500 Invisio® Camera Control Unit) is intended for close visualization of the urinary bladder, renal pelvis and major calyces. The IPN-2505 can be introduced through a percutaneous tract into the kidney and can also be introduced through the urethra to access the bladder. Additional accessories can be used to perform various diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number *K072594*