K 123170

FEB 0 4 2013

510(K) SUMMARY

General Information

Manufacturer	Gyrus ACMI Inc. 136 Turnpike Rd. Southborough, MA 01772-2104 ERN: 3003790304
Contact Person:	Deana Boushell (508) 804-2752 deana.boushell@Olympus-OSTA.com
Date Prepared:	October 28, 2012
Classification Name: Regulation / CFR Citation Number Product Code Class Review Panel	Urological catheter and accessories 876.5130 KNY II Gastroenterology/Urology
Trade Name:	Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath
Generic/Common Name:	Urological catheter and accessories

Predicate Device

The predicate devices include:	
1. Gyrus ACMI Snap-N-Peel™ Introducer	K981611
2. Gyrus ACMI Uropass®	K051593

Intended Use

The Gyrus ACMI Variable Length Access Sheath is intended to be used to permit direct passage of catheters or other devices for the purpose of performing diagnostic and surgical procedures (e.g.,nephrostomy, cystoscopy, ureteroscopy, etc.) in the urinary tract.

Product Description

Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath is a single use, sterile disposable product. The device consists of a sheath (manufactured from PTFE with BiO_3) and dilator (manufactured from HDPE with $BaSO_4$) to facilitate the passage of catheters and other urological devices in the urinary tract. The sheath length is adjustable to the size necessary for the procedure. The dilator is attached to the sheath via a locking leur. The leur connector also allows for injection or irrigation or contrast fluid. For ease of visualization, the dilator and sheath are radiopaque.

Technological features and Substanial Equivalence

The proposed Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath incorporates the same technological features (peel away sheath, tapered dilator and locking mechanism with port) as previously cleared devices.

The proposed Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath has the same Indications for use as previously cleared devices.

The Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath uses similar materials compared to the predicate. The sheath material was changed to PTFE from FTE and though the dilator matieral is the same (HDPE) it is being sourced from a different supplier. These materials have an established history of successful clinical application in Urology. Biocompatibility testing has been performed in compliance to the relevant requirements of ISO-10993.

Nonclinical Testing and Performance Data

Nonclinical testing has been conducted and performance data demonstrates no significant difference in the performance of Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath as compared to predicate devices.

Summary

The proposed Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath, as described in this submission, is substantially equivalent to the predicates in intended use, materials, principles of operation and fundamental scientific technology . Non-clinical testing confirms that no new issues of safety and effectiveness have been raised by the proposed device modifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 4, 2013

Olympus Surgical Technologies America
Gyrus ACMI, Inc.
% Ms. Deana Boushell
Senior Regulatory Specialist
136 Turnpike Road
SOUTHBOROUGH MA 01772

Re: K123170
Trade/Device Name: Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KNY
Dated: December 3, 2012
Received: December 4, 2012

Dear Ms. Boushell:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123170

Device Name: Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath

Indications for Use:

Gyrus ACMI Vari-Pass™ Adjustable Length Access Sheath is intended to be used to permit direct passage of catheters or other devices for the purpose of performing diagnostic and surgical procedures (e.g.; nephrostomy, cystoscopy, ureteroscopy, etc.) in the urinary tract.

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)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123170