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SEP 30 2009

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

**A. SUBMITTER INFORMATION:**

Submitter's Name:	Lumenis, Inc.	5800 G & G Dr
Address:	5302 Betsy Ross Drive	
	Santa Clara, CA 95054	
Contact:	Mike Aymami	
Phone:	408-764-3000	
Fax:	408-764-3999	
Date of Preparation:	June 22, 2009	

**B. DEVICE NAME:**

B.1 – PolyScope Flexible Endoscope

Trade Name(s):	PolyScope Flexible Endoscope
Common/Usual Name:	Flexible Endoscope for diagnosis and treatment in gastroenterology and urology applications
Classification Names:	KOG, Endoscope and accessories FGB. Ureteroscope and accessories, flexible/rigid
CFR Reference:	21 CFR 876.1500, Gastroenterology-Urology Devices, Endoscope and accessories

B.2 PolyScope Xenon Light Source Information

Device Name:	Endoscope and/or accessories
Trade Name(s):	PolyScope Xenon Light Source model LS-200
Common/Usual name:	Xenon Light Source for endoscopy applications
Classification Names:	GCT, Endoscope and accessories
CFR Reference:	21 CFR 876.1500, Gastroenterology-Urology Devices, Endoscope and accessories
Classification Panel:	Gastroenterology/Urology

**C. PREDICATE DEVICE:**

C.1 – PolyScope Flexible Endoscope

1. The Boston Scientific SpyGlass direct visualization probe (K050403).
2. The Olympus VISERA Uretero-Reno Videoscope, Olympus XURF type V - (K072957)

C.2 – PolyScope Xenon Light Source

The Olympus EVIS EXERA Xenon Light Source CLV-160A (K051645)

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**D. DEVICE DESCRIPTION:**

The PolyScope Flexible Endoscope is comprised from two main components: a disposable, flexible, steerable mini-endoscope and a flexible, modular, reusable optical system that is connected to the catheter to allow the visualization of the desired area.

The PolyScope LS 200 XENON-Endoscopic light source provides white examination light (sunlight spectrum) for all endoscopic applications including:

- During video endoscopy.
- During fiber endoscopy.
- During micro-endoscopy.
- During endoscopy using rigid optics.
- During usage of forehead illumination.

**E. INTENDED USE:**

The PolyScope Flexible Endoscope is intended to provide direct visualization for diagnosis and treatment within the bladder, urethra, ureter, and kidney and during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

The PolyScope Xenon Light Source is intended to be used with an endoscope to provide illumination during endoscopic procedures.

**F. TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE STATEMENT:**

The subject device, the PolyScope Flexible Endoscope, has the same intended use, general design and same fundamental scientific technology as the predicate devices (K050403, K072957). Also, the PolyScope Xenon Light Source has the same intended use, general design and same fundamental scientific technology as the predicate device (K051645).

The PolyScope Flexible Endoscope and the PolyScope Xenon Light Source use a technology substantially equivalent to their predicates (K050403, K072957 and K051645 respectively). There are no new hazards or ne question regarding safety and effectiveness introduced by the PolyScope Flexible Endoscope and the PolyScope Xenon Light Source as compared with the predicate devices.

**G. PERFORMANCE DATA SUMMARY:**

The appropriate testing including safety, performance and functional testing to determine substantial equivalence of the PolyScope Flexible Endoscope and the PolyScope Xenon Light Source has been conducted.



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

Mr. Mike Aymami  
Global Director Regulatory and Quality Systems Compliance  
Lumenis, Inc.  
5302 Betsy Ross Drive  
SANTA CLARA CA 95054

SEP 30 2009

Re: K091962  
Trade/Device Name: PolyScope Flexible Endoscope  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: ODF  
Dated: June 29, 2009  
Received: July 1, 2009

Dear Mr. Aymami:

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.

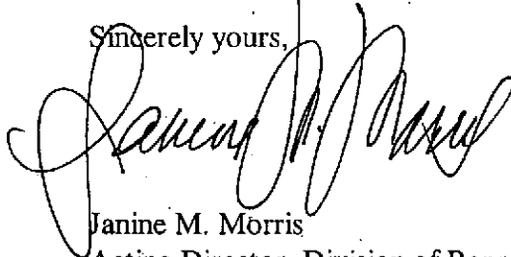
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

**1.3 Indications for Use Statement**

510(k) Number (if known): K091962

Device Name: PolyScope Flexible Endoscope  
PolyScope Xenon Light Source

Indications for Use:

The PolyScope Flexible Endoscope is indicated in flexible endoscopic procedures for diagnostic and therapeutic applications where flexible endoscopes are standard of care including:

- Gastroenterology, including procedure of the Biliary system involving the hepatic and pancreatic ducts.
- Urology, including procedures involving the bladder, ureter, renal pelvis and kidney.

The PolyScope Xenon-Endoscopic light source LS 200 provides white examination light (sunlight spectrum) for all endoscopic applications including:

- During video endoscopy.
- During fiber endoscopy.
- During micro-endoscopy.
- During endoscopy using rigid optics.
- During usage of forehead illumination.

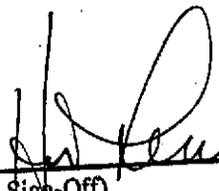
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –  
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CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number   K091962