JAN 3 0 2004

K033651

SMDA 5120(k) SUMMERY

OLYMPUS VIDEO URETEROSCOPE, NTSC

A. Submitter's Name, Address and Phone and Fax Numbers

Name & Address of manufacturer:	Olympus Winter & Ibe, GmbH Kuehnstr. 61 Hamburg 22045, Germany Phone: +49 40 669 66-0 Fax: +49 40 668 15 91
Registration Number:	8010313

B. Name of Contact Person

Address of initial importer and contact	Olympus America 2 Corporate Center Drive Melville, N.Y. 11747
Registration Number:	2429304
Contact:	Tina Steffanie-Oak, Associate R.A. Manager
Phone:	631-844-5477
Fax:	631-844-5554

C. Device name, Common Name, Classification Name and Predicate Devices

Trade NAME:	OLYMPUS VIDEO URETEROSCOPE, NTSC
Common Name:	Ureteroscope and Accessories
Classification: Class II	21 CFR 876.1500 Endoscope and accessories. FDA Product Code FGB
Predicate Device:	A2560 510(k)# K951855

D. Description of the Device

The subject device is used for endoscopic diagnosis and treatment within the urethra, bladder, and ureter. The optical system is modified from image guide to CCD and the resolution is improved.

E. Intended Use of the Device

This instrument has been designed to be used with an Olympus video system, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the urethra, bladder, and ureter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2004

Olympus Winter & Ibe, GmbH
c/o Ms. Tina Steffanie-Oak
Associate Manager, Regulatory Affairs
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747

Re: K033651
Trade/Device Name: OLYMPUS VIDEO URETEROSCOPE, NTSC (S-1546/2)
Modification to A2560 Ureteroscope (K951855)
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FGB
Dated: January 21, 2004
Received: January 22, 2004

Dear Ms. Steffanie-Oak:

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); 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033651

510(k) Number (if known): ~~Not assigned yet~~ K033651

Device Name: Olympus video ureteroscope, NTSC

Indications for Use: This instrument has been designed to be used with an Olympus video system, light source, documentation equipment, display monitor, endo-therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the urethra, bladder, and ureter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

David R. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033651