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

OLYMPUS AMERICA, INC.
Ms. Laura Storms-Tyler
Director, Regulatory Affairs
and Quality Assurance
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K021074
Trade/Device Name: Olympus VISCERA Cystovideoscope Type CYF V/VA
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated (Date on orig SE ltr): March 29, 2002
Received (Date on orig SE ltr): April 2, 2002

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of May 2, 2002.

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 contact 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. 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,

Benjamin R. Fisher -S

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 (if known): K021074

Device Name: Olympus VISCERA Cystovideoscope type CYF V/VA

Indications for Use:

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

(Please do not write below this line. Continue on another page is needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021074

K021074

MAY 02 2002

SMDA 510(k) SUMMARY

VISERA CYSTOVIDEOSCOPE OLYMPUS CYF TYPE V/VA

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

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjuku Monolis Nishi-Shinjuku, Shinjuku-ku Tokyo, Tokyo 163-0914 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers:	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 81- 426-42-2891 FAX 81-426-46-5613

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers:	Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5416

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

Trade Name:	VISERA CYSTOVIDEOSCOPE OLYMPUS CYF TYPE V/VA
Common Name:	Cystofiberscope / Nephrofiberscope, accessories and ancillary equipment
Classification:	21 CFR 876.1500 Endoscope and accessories, 21 CFR 876.4300 Endoscopic electrosurgical unit and accessories, Class II
Predicate Device:	XCYF-1T3 (K# 993041) URF-P2 (K# 912120) BF-200 (K# 931154) LF-TP/DP (K# 981543)

D. Description of the Device(s)

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

E. Intended Use of the Device(s)

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