



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

The Olympus Optical Company  
% Robert Schiff, Ph.D., RAC, CQA (ASQC)  
President  
Schiff & Company  
1129 Bloomfield Avenue  
West Caldwell, NJ 07006

JUL 27 2015

Re: K993041  
Trade/Device Name: Olympus XCYF – 1T3 OES  
Cystofiberscope/Nephrofiberscope  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: FAJ, FGA, FDI, KGE, KNS, FCL  
Dated (Date on orig SE ltr): March 14, 2000  
Received (Date on orig SE ltr): March 15, 2000

Dear Dr. Schiff,

This letter corrects our substantially equivalent letter of March 30, 2000.

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

K993041

**OLYMPUS**

INDICATIONS FOR USE STATEMENT

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

Device Name: Olympus XCYF-1 T3 OES CYSTOFIBESCOPE/  
NEPHROFIBERSCOPE, accessories and ancillary equipment.

Indications for Use:

These instruments have been designed to be used with an Olympus Light Source, Documentation Equipment, Display Monitor, Suction Pump, Endo-Therapy Accessories, electrosurgical Unit, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidneys.

Do not use this instrument for any purpose other than its intended use.

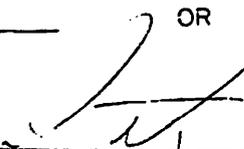
(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use    
 (Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

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

510(k) Number K993041

**OLYMPUS OPTICAL CO., LTD.**

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TEL. (426)42-5101 FAX (426)46-2786

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510(k) Premarket Notification  
Olympus Optical Co., Ltd.  
OES Cystofiberscope/Nephrofiberscope

K993041  
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**510(k) SUMMARY**

**OLYMPUS XCYF-1T3**

**OES CYSTOFIBERSCOPE/NEPHROFIBERSCOPE**

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

Name & Address of manufacturer: Olympus Optical Co., Ltd.  
22-2 Nishi-Shinjuku, 1-Chome,  
Shinjuku-ku, Tokyo 163-8610  
Japan

Registration No: 8010047

Address, Phone and Fax Numbers: 2951 Ishikawa-Cho,  
Hachioji-shi, Tokyo 192-8507, Japan  
R&D Department, Endoscope Division  
Tel: 81-426-42-5101  
Fax: 81-426-46-2786

**B. Name of Contact Person** Tadahiko Ogasawara

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Prepared by Schiff & Company

**C. Trade Name, Common Name, Classification Number, Classification**

Trade Name : Olympus XCYF - 1T3  
OES Cystofiberscope/Nephrofiberscope  
Accessories and Ancillary Equipment

Common Name: Cystofiberscope/Nephrofiberscope  
Classification Number: 21 CFR 876.1500 Endoscopes and  
Accessories

Predicate Device

Classification : K843084 Olympus  
Nephroscope/Cystoscope  
K904940 Infant Resectoscope &  
Accessories

**D. Description of the Device**

The Olympus XCYF-1T3 OES CYSTOFIBERSCOPE/NEPHROFIBERSCOPE has been specifically designed to be used with an Olympus Light Source, documentation, equipment, and display monitor. The XCYF-1T3 is equipped with a large Instrument Channel of bright optical quality compared to the

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predicate device, XCYF-1T3. These characteristics facilitate operation under endoscopic-surgery including high-frequency treatment within the bladder, urethra and kidney.

**E. Intended Use of the Device(s)**

The Olympus XCYF-1T3 OES CYSTOFIBERSCOPE/NEPHROFIBERSCOPE, accessories and ancillary equipment have been specifically designed to be used in endoscopic diagnosis and treatment within the bladder, urethra and kidney. Do not use these instruments for any purpose other than their intended use.

**F. General Safety**

The Olympus XCYF-1T3 OES Cystofiberscope/Nephrofiberscope is manufactured and tested according to voluntary safety standards IEC60601-1 and IEC60601-2-18. XCYF-1T3 is designed for electrosurgical treatment within the bladder, urethra and kidney. When compared to the predicate device, the Olympus Nephroscope/Cystoscope Model CHF-P10, except for the electrosurgical treatment, does not incorporate any significant change in operation, material or design that could affect safety or effectiveness.