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.
% Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Systems NA, Inc.
70 Codman Hill Road
Boxborough, MA 01719

JUL 27 2015

Re: K032092
Trade/Device Name: Olympus XCYF-TP3 Cystofiberscope/Nephrofiberscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, FGA,FCL, FDI, KGE and KNS
Dated (Date on orig SE ltr): July 3, 2003
Received (Date on orig SE ltr): July 7, 2003

Dear Mr. Sherratt,

This letter corrects our substantially equivalent letter of July 16, 2003.

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

510(k) Number(if known): K032092 ~~Not assigned yet~~

Device Name: XCYF-TP3 CYSTOFIBERSCOPE/NEPHROFIBERSCOPE

Indications for Use:

This instrument has been designed to be used with an Olympus Light Source, documentation equipment, display monitor, suction pump, Endo-Therapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032092

K032092

JUL 16 2003

# SMDA 510(k) SUMMARY

## XCYF-TP3, Cysto-Nephrofiberscope,

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

## A. GENERAL INFORMATION

### 1. Applicant

| | |
|---|---|
| Name & Address: | Olympus Optical Co., Ltd.<br>34-3 Hirai Hinode-machi,<br>Nishitama-gun, Tokyo, 190-0182, Japan |
| Registration Number: | 3003637092 |

### 2. Initial Importer

| | |
|---|---|
| Name & Address: | Olympus America Inc.<br>Two Corporate Center Drive, Melville, NY 11747-3157 |
| Registration Number: | 2429304 |

### 3. Submission Correspondence

| | |
|---|---|
| Name : | Masao Wada |
| Address : | Olympus Optical Co., Ltd.<br>2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507, Japan |
| Telephone : | 81-426-42-2891 |
| Facsimile : | 81-426-42-2291 |
| E-mail address : | m_wada@ot.olympus.co.jp |
| Establishment Registration No. : | 8010047 |

## B. DEVICE IDENTIFICATION

### 1. Common/Usual Name

Cystofiberscope/ Nephrofiberscope

### 2.Device Name

XCYF-TP3 Cystofiberscope/ Nephrofiberscope

### 3. Classification Name

| CFR Number | Classification Name | Class | Product Code |
|---|---|---|---|
| 876.1500 | Endoscopes and accessories | II | 78KOG, 78FAJ, 78FGA, FTI |

## C. IDENTIFICATION OF LEGALLY MARKETED DEVICES WHICH WE CLAIM SUBSTANTIAL EQUIVALENCE

The following listed devices are seem to be as predicate devices in consideration of its characteristic and the following table shows regulatory history.

| Model | 510(k)# | Manufacturer | Class | Product Code |
|---|---|---|---|---|
| XCYF-1T3<br>OES Cystrofiberscope/ Nephrofiberscope Accessories and ancillary equipment | #K993041 | Olympus Optical Co., Ltd | II | 78FCL<br>78FAJ<br>78FGA<br>78KOG<br>78FDI<br>78KGE<br>78KNS |
| XENF-DP<br>Laryngofiberscope, its Accessories and ancillary Equipment | #K011869 | Olympus Optical Co., Ltd | II | EOB |

## D. DEVICE DESCRIPTION

### 1. Summary

The subject device, the XCYF-TP3 is basically identical to the predicate device (XCYF-1T3) which is the flexible endoscope for use in the bladder, urethra and kidney.

Subject device may be used with three different Light source as follow;

- A rechargeable powered Miniature Light source, or,
- A battery powered Miniature Light source as predicate device, XENF-DP, or,
- Light guide cable as predicate device, XENF-DP.

In conclusion, this subject device is technically the same as the predicate device, which we describe in the table above.

### 2. Design

XCYF-TP3 has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirement of IEC60601-1, IEC60601-1-1and IEC60601-2-18.

### 3. Materials

All the patient contacting materials used in this endoscope and ancillary equipments are identical materials that have been cleared in the past 510(k) submissions. And all materials have been confirmed with ISO 10993-1.

### 4. Intended Use of the device

This instrument has been designed to be used with the OLYMPUS Light source, Documentation equipment, Display monitor, Endo-Therapy Accessories and other Ancillary Equipment for endoscopic diagnosis and treatment.

### 5. Summary including conclusion drawn form Non-clinical Tests

When compared to the preamendment/predicate device, XCYF-1T3 does not incorporate any significant changes in the intended use, method of operation, material, or designed that could affect the safety effectiveness. Therefore, the clinical data is not necessary for its evaluation of safety and efficacy.