MAY 26 2006

October xx, 2005

510(k) SUMMARY

LAPARO-THORACO VIDEOSCOPE XLTF-VAW

1. General Information

■ Applicant:	Olympus Medical Systems Corp. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No: 8010047
■ Official Correspondent:	Laura Storms-Tyler Executive Director Regulatory Affairs & Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058, USA Phone: 631-844-5688 FAX: 631-844-5554 Email:Laura.storms-tyler@olympus.com Establishment Registration No: 2429304
■ Manufacturer	Olympus Medical Systems Corp. 34-3 Hirai Hinode-machi, Nishitama-gun, Tokyo, 190-0812, Japan Establishment Registration Number: 3003637092

2. Device Identification

■ Device Name	LAPARO-THORACO VIDEOSCOPE XLTF-VAW
■ Common Name	LAPARO-THORACOVIDEOSCOPE
■ Regulation Number	21 CFR 876.1500/884.1720
■ Regulation Name	Endoscope and accessories Gynecologic laparoscope and accessories
■ Regulatory Class	II
■ Product Code	GCJ/HET
■ Classification Panel	Laparoscope, general & plastic surgery Laparoscope, gynecologic (and accessories)

3. Predicate Device Information

(1)	Device Name:	LTF-V LAPARO THORACO VIDEOSCOPE
	Common Name:	LAPARO THORACO VIDEOSCOPE
	510(k) No.	K955403
	Manufacturer:	Olympus Optical Co., Ltd.
(2)	Device Name:	A4907 LENS CLEANING SHEATH
	Common Name:	LENS CLEANING SHEATH
	510(k) No.	K955403
	Manufacturer:	Olympus Optical Co., Ltd.
(3)	Device Name:	GIF-Q160Z EVIS EXERA GASTROINTESTINAL VIDEOSCOPE
	Common Name:	GASTROINTESTINAL VIDEOSCOPE
	510(k) No.	K011151
	Manufacturer:	Olympus Optical Co., Ltd.

4. Device Description

The subject device, LAPARO-THORACO VIDEOSCOPE XLTF-VAW is designed for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

The subject device has a different lens cleaning method from the predicate Olympus LAPARO THORACO VIDEOSCOPE LTF-V. For the predicate device, air and water for lens cleaning are supplied through the space between the endoscope's insertion section and a sheath attached to it. The subject device also uses a sheath but irrigation and insufflation are performed through the inner channels of the videoscope. The basic structure of the inner channel is substantially equivalent to that of the predicate device, GIF-Q160Z.

5. Indications for Use

This instrument has been designed to be used with the VISERA Video System Center OTV-S7V, light source, documentation equipment, videomonitor, endo-thrapy accessories, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

6. Comparison of Technological Characteristics

The XLTF-VAW is basically identical to the predicate device in intended use, and similar in specifications except for the addition of endoscope inner channel. Comparison between the subject and predicate devices is shown in Table 1.

Table 1. Comparison of Specifications

Specifications	Subject Device XLTF-VAW	Predicate Device LTF-V	Predicate Device GIF-Q160Z
Field of View	90°	70°	140° (WIDE) 75° (TELE)
Depth of Field	15~100 mm	18~100 mm	8~100 mm(WIDE) 1.5~3 mm(TELE)
Direction of View	0° Forward Viewing	0° Forward Viewing	0° Forward Viewing
Outer Diameter of Distal End	ϕ 10.5 mm	ϕ 11.0 mm	ϕ 10.8 mm
Bending Section Angulation UP/DOWN	100° /100° /60° /60°	90° /90° /90° /90°	210° /90° /100° /100°
Working Length	330 mm	330 mm	1,030 mm
Endoscope inner channel	Provided	Not provided	Provided

7. Conclusion

When compared to the predicate device, the XLTF-VAW does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 26 2006

Olympus Medical Systems Corporation
c/o Ms. Laura Storms-Tyler
Executive Director, Regulatory Affairs
and Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-9058

Re: K053382
Trade/Device Name: Laparo-Thoraco Videoscope, Model XLTF-VAW
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Product Code: HET
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Code: GCJ
Regulatory Class: II
Dated: May 5, 2006
Received: May 9, 2006

Dear Ms. Storms-Tyler:

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 (Premarket Approval), it may be subject to such 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K053382

Device Name: LAPARO-THORACO VIDEOSCOPE XLTF-VAW

Indications For Use:

This instrument has been designed to be used with the VISERA Video System Center OTV-S7V, light source, documentation equipment, videomonitor, endo-thrapy accessories, electrosurgical unit, and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lingren

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053382