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OLYMPUS

510(k) SUMMARY

SEP 2 6 2008

EVIS EXERA II 180 SYSTEM

1. General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan
  Establishment Registration No: 8010047

- Official Correspondent: Laura Storms-Tyler
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway, PO Box 610
  Center Valley PA 18034-0610
  Phone: (484) 896-5688
  Facsimile: (484) 896-7128
  Email:Laura.storms-tyler@olympus.com
  Establishment Registration No: 2429304

- Manufacturer:: Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No.: 9610595

2. Device Identification

- Device Name: HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH
- Common Name: Laparo-Thoraco Videoscope
- Class: II
  Regulation Number / Name: 21 CFR 884.1720 Gynecologic laparoscope and accessories
  21 CFR 876.1500 Endoscope and accessories

- Product Code: GCJ/ HET/ NWB
- Classification Panel: Obstetrics/ Gynecology
  Gastroenterology/ Urology,

3. Legally Marketed Device to which Substantial Equivalence is Claimed

The following table shows the subject and predicate device to which we claim substantial equivalence.

Subject & Predicate Devices

Subject Device (part of this submission)	Predicate Device	PD's 510(k) No.
HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH LTF-VH	OES Laparo-Thoraco Videoscope Type V LTF-V	K955403

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4. Device Description

The HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH is a flexible video endoscope used for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs which is basically identical to the predicate devices, LTF-V, for the same application areas.
The major difference from the predicate device is only the NBI function added to the subject device.The new endoscope is basically identical to the predicate device shown in above Table in intended use, and similar in specifications, performance without NBI observation..

When the CLV-180 and CV-180 are combined with the new LTF-VH, both an endoscopic image by white light illumination and that by NBI illumination can be observed within the thoracic and abdominal cavities including female reproductive organs. The CV-180 identifies a NBI-compatible scope when it is connected by using the Scope ID function provided with the scopes.

5. Indications for Use

HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH:
This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit,and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities.

6. Comparison of Technological Characteristics

The LTF-VH is mainly similar to the predicate device, LTF-V in specifications without NBI fuinction.
Comparison between the subject and predicate devices is shown below.

Comparison of Specifications

Specifications	Subject Device LTF-VH	Predicate Device LTF-V (K955403)
Field of View	90°	70°
Direction of View	0°	0°
Optical System	color	color
Angulation	UP : 100° DOWN : 100° RIGHT : 100° LEFT : 100°	UP : 90° DOWN : 90° RIGHT : 90° LEFT : 90°
Working Length	370mm	330mm
Inner Diameter of Instrument Channel	NA	NA
ON/OFF switch for NBI function	Provided	Not provided

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6. Conclusion

When compared to the predicate devices, the LTF-V 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

Ms. Laura Storms-Tyler
Vice President
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K080948
Trade/Device Name: HD EndoEYE Laparo-Thoraco Videoscope
OLYMPUS LTF Type VH
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET, GCJ and NWB
Dated: August 27, 2008
Received: August 28, 2008

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 (PMA), 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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting 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): K080948
Device Name: HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH

This instrument has been designed to be used with a video system center, light source, documentation equipment, monitor, hand instruments, electrosurgical unit,and other ancillary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080948