K111788

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JAN 13 2012

January 13, 2012

1. General Information

■ **Applicant**	Olympus Winter & Ibe GmbH Kuehnstrasse 61 * 22045 Hamburg * Germany Establishment Registration No: 9610773
■ **Official Correspondent**	Stacy Abbatiello Kluesner, RAC Regulatory Affairs & Quality Assurance Olympus America Inc. 3500 Corporate Parkway, PO Box 610 Center Valley PA 18034-0610 Phone: (484) 896-5405 Facsimile: (484) 896-7128 Email: Stacy.kluesner @olympus.com Establishment Registration No: 2429304
■ **Manufacturer**	Olympus Winter & Ibe GmbH Kuehnstrasse 61 * 22045 Hamburg Germany Establishment Registration Number: 9610773

2. Device Identification

■ **Device Name**	Olympus EndoEYE HD II
■ **Common Name**	High Definition Digital Video Laparoscope
■ **Regulation Number**	21 CFR 876.1500 21 CFR 874.4720 21 CFR 884.1720
■ **Regulation Name**	Endoscope and Accessories Mediastinoscope and Accessories Gynecologic Laparoscope and Accessories
■ **Regulatory Class**	II
■ **Product Code**	GCJ /NLM/KOG/ NWB EWY NMH/HET
■ **Classification Panel**	Gastroenterology/Urology Ear Nose& Throat Obstetrics/Gynecology

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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 Device (Part of this submission)	Predicate Device	PD's 510(k) No.
HD EndoEYE II - WA50040A, 10 mm, 0°, autoclavable - WA50042A, 10 mm, 30°, autoclavable - WA50050A, 5.4 mm, 0°, autoclavable - WA50052A, 5.4 mm, 30°, autoclavable	HD EndoEYE WA50011A, WA50013A, WA50013L, WA50013T, WA50015L	K090980
	HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF-VH	K080948

Table 1. Subject & Predicate Devices

4. Device Description

The ENDOEYE HD II - High Definition Digital Video Laparoscope is a video endoscope used for endoscopy and endoscopic surgery within the abdominal cavities, which is basically identical to the predicate devices for the same application areas.

5. Indications for Use

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 including the female reproductive organs.

6. Comparison of Technological Characteristics

The subject EndoEYE HD II is nearly identical to the predicate HD EndoEYE device. It has identical spefications to the predicate device except for; (1) a wider field of view, (2) incorpotion of a Fog Free Function, (3) a greater range in the depth of field and (4) multible CCDs.

Specifications	Subject Device	Predicate Device	Predicate Device

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		K090980	K080948
Device name	**EndoEYE HD II**	**HD EndoEYE**	HD EndoEye Laparo-Thoraco Videoscope
510(k) number		K955456	K080948
Type	WA50040A, WA50042A, WA50050A, WA50052A	WA50011A, WA50013A, WA50013L, WA50013T, WA50015L	LTF-VH
Field of View	90°	80°	90°
Depth of field	20 to 200 mm	10 to 120 mm	15-100 mm
Direction of View	0°, 30°	0°, 30°, 45°	0°
Outer Diameter of Distal End	5.4 mm, 10mm	10 mm	10 mm
Optical System	Color	Color	Color
Working Length	325 or 300 mm	250 – 390 mm	370 mm
Switch for NBI function	Provided	Provided	Provided
Number of CCD chips	2 (WA50040A & WA50042A) 1 (WA50050A & WA50052A)	1	1

7. Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Reprocessing validation was carried out in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance - April 1996."

The subject device has identical materials as the predicate device.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

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The following standards have been applied to the subject EndoEYE HD II devices:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971
- DIN EN ISO 17664
- DIN EN ISO 17665-1
- DIN EN ISO 14161
- ISO 11138, part 3
- DIN EN 556-1, Part 1
- DIN EN 285

Performance testing conducted included validation of the Fog Free function, verification testing for resolution and color correctness, spectrum analysis and testing to confirm the durability of the device after multiple sterilization cycles.

8. Conclusion

When compared to the predicate devices, the ENDOEYE HD II 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 and therefore is substantially equivalent to the idenfied predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Olympus Winter & Ibe GmbH
% Ms. Stacy Abbatiello Kluesner, M.S., RAC
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Olympus America Inc.
3500 Corporate Parkway
CENTER VALLEY PA 18034

JAN 13 2012

Re: K111788
Trade/Device Name: ENDOEYE HD II
Type WA50040A, WA50042A, WA50050A, WA50052A
Regulation Number: 21 CFR§ 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: January 10, 2012
Received: January 11, 2012

Dear Ms. Kluesner:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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, 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

510(k) Number (if known): K111788

Device Name: ENDOEYE HD II
Type WA50040A, WA50042A, WA50050A, WA50052A

Indications For Use:

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 including the female reproductive organs.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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, Gastro-Renal, and Urological Devices
510(k) Number K111788