

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.
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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	HD EndoEYE WA50011A, WA50013A, WA50013L, WA50013T, WA50015L	K090980
- WA50042A, 10 mm, 30°, autoclavable - WA50050A, 5.4 mm, 0°, autoclavable - WA50052A, 5.4 mm, 30°, autoclavable	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 specifications to the predicate device except for; (1) a wider field of view, (2) incorporation of a Fog Free Function, (3) a greater range in the depth of field and (4) multiple 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 identified predicate devices.



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
Project Manager
Olympus America Inc.
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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.

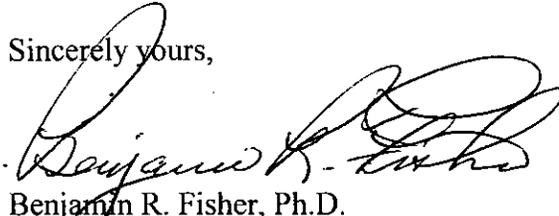
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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: ENDO EYE 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.

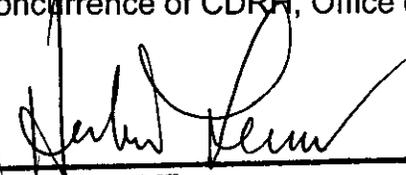
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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

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