August 29, 2019

Olympus Winter & Ibe GmbH
Sheri Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley, PA 18034-061

Re: K190744
Trade/Device Name: ENDOEYE HD II (WA50040A, WA50042A, WA50050A, WA50052A)
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET, GCJ, NWB
Dated: July 29, 2019
Received: July 30, 2019

Dear Sheri Musgnung:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Sharon Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K190744

Device Name
ENDOEYE HD II (WA50040A, WA50042A, WA50050A, WA50052A)

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

510(k) Summary of Safety and Effectiveness

**August 26, 2019**

## 1 General Information

Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg
Germany
Establishment Registration Number: 9610773

Official Correspondent:
Sheri L Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley PA 18034-061
Phone: 484 896-3147
Email: sheri.musgnung@olympus.com

Establishment Registration Number: 2429304

## 2 Device Identification

| | |
|---|---|
| Proprietary /Trade Name: | ENDOEYE HD II (WA50040A, WA50042A, WA50050A, WA50052A) |
| Classification name: | Laparoscope, Gynecologic and accessories |
| Regulations Number: | 21 CFR 884.1720 |
| Regulatory class: | II |
| Product code: | HET<br>GCJ / NWB |
| Review Panel: | Obstetrics and Gynecology |

## 3 Predicate Device

Olympus K111788, ENDOEYE HD II

The predicate has been subject to a design related recall.

## 4 Product Description

The ENDOEYE HD II - High Definition Digital Video Laparoscope is a rigid video telescope used for endoscopic diagnosis, treatment, video observation and surgery within the thoracic and abdominal cavities including female reproductive organs. For laparoscopic applications, the video telescope is inserted via a trocar into the patient.

The ENDOEYE HD II is used with a video system center, light source and monitor to achieve its intended function.

In addition, the ENDOEYE HD II can be inserted in compatible instrument trays for reprocessing.

The ENDOEYE HD II can provide an image with either white light or narrow band imaging and

WA50040A and WA50042A include a heater function at the distal tip to reduce fogging of the lens.

## 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.

The ENDOEYE HD II has the same intended use as the predicate device.

## 6 Technological Characteristics

The ENDOEYE HD II has the same technological characteristics as the predicate device.

| Device | Subject device | Predicate device |
|---|---|---|
| **Device Name** | EndoEYE HD II | EndoEYE HD II |
| **Model Number** | WA50040A, WA50042A<br>WA50050A, WA50052A | WA50040A, WA50042A<br>WA50050A, WA50052A |
| **510(k) number** | Not yet known | K111788 |

| Device | Subject device | Predicate device |
|---|---|---|
| **Field of view** | WA50040A, WA50042A: 90° ± 9° (at 16:9 aspect ratio)<br>WA50050A, WA50052A: 80.4° ± 8° (at 5:4 aspect ratio) | WA50040A, WA50042A: 90° ± 9° (at 16:9 aspect ratio)<br>WA50050A, WA50052A: 80.4° ± 8° (at 5:4 aspect ratio) |
| **Depth of field** | 21 to 200 mm | 21 to 200 mm |
| **Direction of viewing (forward)** | WA50040A, WA50050A: 0°±10°<br>WA50042A, WA50052A: 30°±10° | WA50040A, WA50050A: 0°±10°<br>WA50042A, WA50052A: 30°±10° |
| **Type of CCD chip** | Color CCD | Color CCD |
| **Number of CCD chip** | 2 | 2 |
| **Outer diameter of distal end** | Ø 10 mm (WA50040A, WA50042A)<br>Ø 5.4 mm (WA50050A, WA50052A) | Ø 10 mm (WA50040A, WA50042A)<br>Ø 5.4 mm (WA50050A, WA50052A) |
| **Outer diameter of insertion tube maximum** | WA50040A: 10.07 mm<br>WA50042A: 10.2 mm<br>WA50050A: 5.45 mm<br>WA50052A: 5.45 mm | WA50040A: 10.07 mm<br>WA50042A: 10.2 mm<br>WA50050A: 5.45 mm<br>WA50052A: 5.45 mm |
| **Working length** | WA50040A: 325 ± 5 mm<br>WA50042A: 330 ± 1 mm<br>WA50050A: 300 ± 0.5 mm<br>WA50052A: 302± 1 mm | WA50040A: 325 ± 5 mm<br>WA50042A: 330 ± 1 mm<br>WA50050A: 300 ± 0.5 mm<br>WA50052A: 302± 1 mm |
| **NBI observation** | available | available |
| **Heater functionality** | WA50040A,<br>WA50042A: Yes<br>WA50050A,<br>WA50052A: No | WA50040A,<br>WA50042A: Yes<br>WA50050A,<br>WA50052A: No |
| **Autoclavability** | yes | yes |

The subject devices have equivalent technology, performance, dimensions and materials. The differences to the predicate device ENDOEYE HD II are:

- Addition of a printed circuit board (PCB) containing a supervisor circuitry and a second temperature sensor
- Updated Instructions for Use.

The above described differences in technological characteristics do not raise different questions of safety and effectiveness.

## 7 Performance Data

The following Design verification and validation testing was performed on the subject device:

- Electrical safety as per IEC 60601-1 Edition 3.1 and IEC 60601-2-18 Edition 3.0
- Electromagnetic compatibility (EMC) as per IEC 60601-1-2 Edition 4.0
- Thermal Safety as per IEC 60601-1 Edition 3.1 and IEC 60601-2-18 Edition 3.0
- Mechanical performance testing as per ISO 8600-3 Edition 1, ISO 8600-4 Edition 2 and ISO 8600-5 Edition 1
- Transport and shipping testing as per ASTM D4169-16
- Tests related to the expected service life as per IEC 60601-1 Edition 3.1 and IEC 60601-2-18 Edition 3.0
- Testing of the illumination system as per IEC 60601-1 Edition 3.1 and IEC 60601-2-18 Edition 3.0
- Software Verification as per IEC 62304 Edition 1.1
- Usability Validation of the Instructions for Use as per FDA Guidance Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Risk analysis was carried out in accordance with established internal acceptance criteria based on ISO 14971:2007.

All samples tested met their predefined acceptance criteria.

## 8 Conclusion

The performance data support the safety of the device and demonstrate that the subject devices comply with the recognized standards as specified and support a substantial equivalence determination.