K102379

510(k) SUMMARY

JAN - 5 2011

LTF-Y0009, XOEV-3D1, MAJ-Y0041
3D Laparo-Thoraco Videoscope, Polarized 3D Monitor, 3D Video Mixer

October 21, 2010

1 General Information

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

- Official Correspondent: Stacy Abbatiello Kluesner, M.S., RAC
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5405
  FAX: 484-896-7128
  Email: stacy.kluesner@olympus.com

- Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP. Hinode Plant
  34-3 Hirai, Hinode-cho, Nishitama-gun,
  Tokyo, 190-0182, Japan
  Establishment Registration No.:3003637092

2 Device Identification

- Device Trade Name: LTF-Y0009,
  XOEV-3D1,
  MAJ-Y0041

- Common Name: 3D Laparo-Thoraco Videoscope,
  Polarized 3D Monitor,
  3D Video Mixer

- Regulation Number: 876.1500
  884.1720
  874.4720

- Regulation Name: Endoscope and accessories
  Gynecologic laparoscope and accessories
  Mediastinoscope and accessories

- Regulatory Class: II

- Classification Panel: Gastroenterology and urology,
  Obstetrics/Gynecology

General & Plastic Surgery

- Product Code: FCG, FAL, HET, GCJ, and NWB

3 Predicate Device Information

- Device Name: 3D Laparoscope A5300 – Urology , Ob/Gyn, General Surgery
  HD EndoEYE Laparo-Thoraco Videoscope OLYMPUS LTF Type VH
- Common Name: 3D Laparoscope
  Laparo-Thoraco Videoscope
- Manufacturer: Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-lidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No.: 9610595
- 510(k) No. 3D Laparoscope - Urology (K943304)
  3D Laparoscope - Ob/Gyn (K943305)
  3D Laparoscope - General Surgery (K943307)
  LTF-VH (K080948)

4 Device Description

3D Laparo-Thoraco Videoscope (LTF-Y0009) is a video endoscope used for endoscopy and endoscopic surgery within the peritoneal and thoracic cavity. LTF-Y0009 is basically identical to predicate device 3D Laparoscope, for the same application areas.
The 3D video observation of this system is implemented with following process. The captured signals from two CCDs which correspond to left and right eye incorporated in distal end of the subject LTF-Y0009 are transferred to the MAJ-Y0041 via CV-Y0001. CV-Y0001 converts the captured signals into video image signals, and transmits them to the MAJ-Y0041. The MAJ-Y0041 converts the image signals into 3D video signal and transfers it to the XOEV-3D1. On the XOEV-3D1, 3D video image is displayed as passive stereo type which has different polarizing angle in the left and right; therefore, the MAJ-Y0108 is required to obtain 3D video image. The MAJ-Y0108's glasses have polarizing films on them which correspond to their each polarizing angle and it enables 3D observation to the users.

5 Indications for Use

- LTF-Y0009 (3D Laparo-Thoraco Videoscope)
This instrument has been designed for use in conjunction with light source, video system centers, 3D Video Mixer, 3D monitor, documentation equipment, hand instruments, and other ancillary equipment for endoscopy and endoscopic surgery within the peritoneal and thoracic cavity.

- MAJ-Y0041 (3D Video Mixer)
This instrument has been designed to be used with Olympus 3D Laparo-Thoraco videoscope and Video System Center for 3D video observation.

- XOEV-3D1(Polarized 3D Monitor)
This instrument has been designed to be used with Olympus 3D Laparo-Thoraco videoscope, light source, video system center and 3D Video Mixer for endoscopic diagnosis and video observation.

- MAJ-Y0108 (3D glasses)
This instrument has been designed to be used with Olympus 3D Laparo-Thoraco videoscope, light source, video system center, 3D Video Mixer and 3D monitor for 3D video observation.

6 Comparison of Technological Characteristics

The LTF-Y0009, XOEV-3D1, MAJ-Y0041 is basically identical to the predicate device in intended use, and similar in specifications except for the optical system of the subject LTF-Y0009.

7 Conclusion

When compared to the predicate device, the LTF-Y0009, XOEV-3D1, MAJ-Y0041 do 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

Public Health Service

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

Olympus Medical Systems Corporation
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Stacy Abbatiello Kluesner, M.S., RAC
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P.O. Box 610
Center Valley, Pennsylvania 18034-0610

JAN - 5 2011

Re: K102379
Trade/Device Name: 3D Laparo-Thoraco Videoscope; Polarized 3D Monitor; 3D Video Mixer; 3D Glasses
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 28, 2010
Received: December 29, 2010

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K102379 JAN - 5 2011

Device Name: 3D Laparo-Thoraco Videoscope

Indications For Use:

This instrument has been designed for use in conjunction with light source, video system centers, 3D video mixer, 3D monitor, documentation equipment, hand instruments, and other ancillary equipment for endoscopy and endoscopic surgery within the peritoneal and thoracic cavity.

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

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Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102379

Indications for Use

510(k) Number (if known): K102379 JAN - 5 2011
Device Name: 3D VIDEO MIXER

Indications For Use:

This instrument has been designed to be used with Olympus 3D Laparo-Thoraco videoscope and video system center for 3D video observation.

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

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510(k) Number K102379

Indications for Use

JAN - 5 2011

510(k) Number (if known):K102379
Device Name: POLARIZED 3D MONITOR

Indications For Use:

This instrument has been designed to be used with Olympus 3D Laparo-Thoraco videoscope, light source, video system center and 3D video mixer for endoscopic diagnosis and video observation.

Prescription Use___√___ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Mark N. Melkerson for mkm
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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102379

Indications for Use

510(k) Number (if known):K102379

JAN - 5 2011

Device Name: 3D glasses

Indications For Use:

This instrument has been designed to be used with Olympus 3D Laparo-Thoraco videoscope, light source, video system center, 3D Video Mixer and 3D monitor for 3D video observation.

Prescription Use___√___ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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and Restorative Devices

510(k) Number K102379