K081173

DEC 23 200

510(k) SUMMARY

ENDOSCOPIC CO_2 REGULATION UNIT UCR

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
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
FAX: 484-896-7128
Email:Laura.storms-tyler@olympus.com
Establishment Registration No: 2429304

Manufacturer:

Shirakawa Olympus Co., Ltd.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, JAPAN 961-8061
Establishment Registration Number: 3002808148

2 Device Identification

- Device Trade Name: UCR ENDOSCOPIC CO_2 REGULATION UNIT
- Common Name: ENDOSCOPIC CO_2 REGULATION UNIT
- Regulation Number: 21 CFR 876.1500/884.1720
- Regulation Name: Endoscope and accessories

  Gynecologic laparoscope and accessories
- Regulatory Class: II
- Classification Panel: Laparoscope, gynecologic (and accessories)
- Product Code: GCJ/HET

3 Predicate Device Information

(1)	Device Name:	MAJ-1203 Air/Water Supply Pump Unit
	Common Name:	Air/Water Supply Pump Unit
	510(k) No.	Part of submission of K053382
	Manufacturer:	Olympus Optical Co., Ltd.

4 Device Description

The subject UCR Endoscopic CO2 Regulation Unit feeds either CO_2 gas and water to clean the distal end of the XLTF-VAW Laparo-Thoraco Videoscope. The UCR unit is similar to the predicate Olympus device, the MAJ-1203 Air/Water Supply Pump unit, with the following being the major differences:

- The UCR is designed for CO_2 gas and water feeding to clean the distal end of the XLTF-VAW, whereas the predicate device MAJ-1203 was designed for air and water feeding for the XLTF-VAW.
- The UCR utilizes a decompression valve mechanism for gas dispensing, whereas the design for the predicate device MAJ-1203 employs a diaphragm pump.

The Laparo-Thoraco Videoscope XLTF-VAW is designed to be used with a VISERA video system center OTV-S7V, light source, documentation equipment, video monitor, endo-therapy accessories, electrosurgical unit and other anciliary equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities. Olympus has clearance of this system under K053382

5 Indications for Use

The Endoscopic CO_2 Regulation Unit UCR is indicated for use as an accessory to the Olympus XLTF-VAW Laparo-thoraco Videoscope and other ancillary equipment for CO_2 gas and water feeding to clean the distal lens during endoscopic surgery.

6 Comparison of Technological Characteristics

The UCR is basically identical to the predicate device in intended use, and similar in specifications except for the feeding gas, feeding pressure indicator and timer function. Comparison between the subject and predicate devices is shown in Table 1.

Table 1. Comparison of Specifications
Subject Device: Endoscopic CO_2 Regulation Unit UCR
Predicate Device: Air/Water Supply Pump Unit MAJ-1203 (K053382)

The following table is a comparison between the subject device and predicate device.

Items	Subject Device	Predicate Device
	UCR Endoscopic CO_2 Regulation Unit	MAJ-1203 Air/Water Supply Pump Unit
510(k) Number	–	K053382
Dimensions (WxDxH)	130(w) x 156(H) x 334(D) (mm)	85(w) x 155(H)x 191(D) (mm)
Feeding gas	CO_2	Air
Feeding method	Decompression valve	Diaphragm pump
Feeding pressure indicator	Five level LED indication	None
Timer function	Provided	None

7 Conclusion

When compared to the predicate device, the Endoscopic CO_2 Regulation Unit 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

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

Re: K081173
Trade/Device Name: Endoscopic CO_2 Regulation Unit UCR
Regulation Number: 21 CFR §884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: December 4, 2008
Received: December 5, 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): K08 1173

Device Name: UCR

Indications for Use:

ENDOSCOPIC CO_2 REGULATION UNIT UCR

This instrument has been designed to be used with Olympus XLTF-VAW Laparo-Thoraco Videoscope and other ancillary equipment for CO_2 gas and water feeding to clean the distal lens during endoscopic surgery.

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 K081173