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510(k) SUMMARY

HIGH FLOW INSUFFLATION UNIT
UHI-4

October 3, 2011

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:

SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun
Fukushima, JAPAN 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: HIGH FLOW INSUFFLATION UNIT UHI-4
- Common Name: INSUFFLATOR
- Regulation Number: 21 CFR 884.1730
- Regulation Name: Laparoscopic insufflator
- Regulatory Class: II
- Classification Panel: Obstetrics/Gynecology, Cardiovascular
- Product Code: HIF, OSV

3 Predicate Device Information

1

■ Device Name:	45L CORE Insufflator F114
■ Common Name:	Carbon Dioxide Insufflator for Laparoscopy and Endoscopic Vessel Harvesting
■ Manufacturer:	W. O. M. WORLD OF MEDICINE AG
■ 510(k) No.	K063367

2

■ Device Name:	HIGH FLOW INSUFFLATION UNIT UHI-3
■ Common Name:	INSUFFLATOR
■ Manufacturer:	OLYMPUS MEDICAL SYSTEM CORP.
■ 510(k) No.	K014166

4 Device Description

The subject device , UHI-4, has new insufflation function, small mode, for insufflation of cavities along the saphenous vein and radial artery. Therefore, the insufflation pressure of small mode is designed to be less than the normal mode which is implemented in UHI-3.

- The small mode is not intended for pediatric use.
- This subject device has user-friendly displays for indicating gas flow rate, cavity pressure, and insufflated CO_2 gas volume on the front panel of UHI-4.
- It has several safety functions, such as follows:
  - warning lamps
  - alarms for excessive pressure and tube obstruction
  - suction activated for excessive pressure.
- Gas pressure is controlled by reading sensors and switching valves.
- It has a function for evacuating smoke (clearing the field of vision) when either an Electro Surgical Instrument or Ultrasonic Surgical Instrument is used during the operation. This

function may be controlled with an optional foot switch

- A FlexRay interface enables the UHI-4 to communicate its setting data, measured values, and other parameters between UHI-4 and the SonoSurg Generator SonoSurg-G2 or the ELECTROSURGICAL UNIT UES-40.

The standard set of HIGH FLOW INSUFFLATION UNIT UHI-4 consists of an INSUFFLATION TUBE MAJ-590, a SUCTION TUBE MAJ-591 and a CYLINDER HOSE (PIN) FOR UHI-3 MAJ-1080.

5 Indications for Use

This instrument has been designed for insufflation of abdominal cavity, and provides automatic suction and smoke evacuation to facilitate laparoscopic observation, diagnosis and treatment.
This instrument is also designed for controlled CO_2 insufflation to create a cavity along the saphenous vein and/or radial artery to facilitate observation during an endoscopic vessel harvesting procedure.

6 Comparison of Technological Characteristics

The HIGH FLOW INSUFFLATION UNIT UHI-4 is basically identical to the predicate device UHI-3 (K014166) in intended use except for the ability to create small cavities along the saphenous vein/or and radial artery. It is also similar in specifications except for the addition of small mode and expanding the upper flow rate limit in normal mode.

The HIGH FLOW INSUFFLATION UNIT UHI-4 is basically identical to the predicate device 45L CORE Insufflator F114 (K063367) for the Indication for Use to create a cavity along the saphenous vein and/or radial artery during endoscopic vessel harvesting procedures.

7 Summary of nonclinical testing

Bench testing demonstrates that UHI-4 performs safely and functionally by proving that UHI-4 can control each proper setting pressure as demonstrated in clinical articles. Bench tests were conducted to verify the functionality of the UHI-4 setting used for each anatomical site indicated. Brief summaries of the tests are listed below.

- Insufflation in endoscopic harvest of saphenous vein via CABG Applicator.

  It was confirmed that UHI-4 can control the pressure in an environment saphenous vein model

and the acceptance criteria was met.

- Insufflation in endoscopic harvest of radial artery via CABG Applicator.

  It was confirmed that UHI-4 can control the pressure in an environment radial artery model and the acceptance criteria was met.

- Simulated use testing to demonstrate that the UHI-4 can accurately deliver CO_2 at the specified flow rates and pressure settings and that the UHI-4 provides protection from over pressurization.

The results from the tests above demonstrate that UHI-4 can properly control each setting pressure and function as intended.

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.

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 "Major Level of Concern."

The following standards have been applied to the subject UHI-4:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- ISO 14971
- IEC 60601-1-8

8 Conclusion

When compared to the predicate devices, the HIGH FLOW INSUFFLATION UNIT UHI-4 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Olympus Medical Systems Corporation
% Ms. Stacy Abbatiello Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034

NOV 18 2011

Re: K110294
Trade/Device Name: HIGH FLOW INSUFFLATION UNIT UHI-4
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, OSV
Dated: November 16, 2011
Received: November 17, 2011

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,

Herbert P. Lerner, M.D., Director (Acting)
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): K110294

Device Name: HIGH FLOW INSUFFLATION UNIT UHI-4

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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, Gastro-Renal, and Urological Devices
510(k) Number K110294