K122180

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Attachment 10.

510(k) SUMMARY

HIGH FLOW INSUFFLATION UNIT UHI-4

1. General Information

■ Applicant:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507 Establishment Registration No: 8010047
■ Official Correspondent:	Daphney Germain-Kolawole Regulatory Affairs Project Manager Olympus America Inc. 3500 Corporate Parkway PO Box 610 Center Valley, PA 18034-0610, USA Phone: 484-896-5691 FAX: 484-896-7128 Email:daphney.germain-kolawole@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 and 876.1500
■ Regulation Name:	Laparoscopic insufflators Endoscope and accessories
■ Regulatory Class:	II

- Classification Panel: Obstetrics/Gynecology
  Cardiovascular
  Gastroenterology / Urology
- Product Code: HIF, OSV, and FCX

3. Predicate Device Identification

3.1 Predicate Device 1

- Device Name: HIGH FLOW INSUFFLATION UNIT UHI-4
- Common Name: INSUFFLATOR
- Manufacturer: OLYMPUS MEDICAL SYSTEM CORP.
- 510(k) No. K110294

3.2 Predicate Device 2

- Device Name: TRANSANAL ENDOSCOPIC MICROSURGERY (TEM) COMBINATION SYSTEM AND INSTRUMENT SET, INSTRUMENT SET FOR THE TRANSANAL ENDOSCOP
- Common Name: Transanal Endoscopic Surgical Insufflator System and Instrument Set
- Manufacturer: RICHARD WOLF MEDICAL INSTRUMENTS CORP.
- 510(k) No. K000180

4. Device Description

The HIGH FLOW INSUFFLATION UNIT UHI-4 is intended to insufflate the abdominal cavity, and provides automatic suction and smoke evacuation to facilitate laparoscopic observation, diagnosis and treatment. This instrument is intended 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. This instrument is used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment

The HIGH FLOW INSUFFLATION UNIT UHI-4 has the following system functions which are identical to the predicate device:

- **Cavity mode**
  Two modes including "Normal" and "Small" can be selected according to the cavity size.

- **Adjustment of the cavity pressure**
  The pressure inside the cavity can be set in the range between 3 and 25 mmHg (or max. 15 mmHg in the Small cavity mode).

- **Adjustment of the gas flow rate**
  The CO2 flow rate can be set in the range from 0.1 – 45 l/min. (or max. 10 l/min. in the Small cavity mode). Three flow rate modes including "High", "Medium" and "Low" can be selected with a one-touch operation.

- **Display mode**
  The information displayed on the front panel can be limited as required by the user.

- **Relief mode**
  When the cavity pressure exceeds the set value by 5 mmHg or more, the relief mode is activated to open the channels inside the instrument and release the internal gas until the cavity pressure drops to the set value. The relief mode can be set to ON or OFF as required. Default set value is ON.

- **Smoke evacuation**
  When the MAJ-1939 foot switch for smoke evacuation (optional) is used, the smoke and mist generated inside the cavity can be exhausted while maintaining the cavity pressure at a constant level.

- **Automatic smoke evacuation**
  The smoke evacuation operation can be interlocked with the output of Olympus generator units such as the SonoSurge-G2, UES-40, ESG-400 and USG-400.

The functions of the subject HIGH FLOW INSUFFLATION UNIT UHI-4 are the same as those of the predicate devices described above.

5. Indications for Use

This instrument is intended to insufflate the abdominal cavity, and provides automatic suction and smoke evacuation to facilitate laparoscopic observation, diagnosis and treatment.
This instrument is intended 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.
This instrument is used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment.

6. Comparison of Technological Characteristics

The intended use of the HIGH FLOW INSUFFLATION UNIT UHI-4 is identical to the predicate device (K110294) except for the ability to use the device in the colon to facilitate endoscopic observation, diagnosis and treatment. Therefore, the HIGH FLOW INSUFFLATION UNIT UHI-4 with expanded indications for use has the same technological characteristics as the predicate device as follows:

- Operating principle
- Dimensional specifications
- Electrical characteristics
- Mechanical characteristics
- Communication characteristics
- Energy source
- Material (no patient contacting material)

7. Summary of non-clinical testing

Bench testing was performed to support that the HIGH FLOW INSUFFLATION UNIT UHI-4 performed safely and functionally for the expanded indications for use. The following tests were conducted to verify the performance of the UHI-4 in the colon:

- Validation of the Rectal Cavity Model
- Insufflation Control
- Pressure Measurement
- Overpressure Protection

The acceptance criteria were met in the tests conducted. The results of these tests indicate that, when used in the colon under the recommended insufflation settings, the HIGH FLOW INSUFFLATION UNIT UHI-4 performs as intended.

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. In summary, the HIGH FLOW INSUFFLATION UNIT UHI-4 with expanded indications for use described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 13, 2012

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034

Re: K122180
Trade/Device Name: HIGH FLOW INSUFFLATION UNIT UHI-4
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX, HIF, OSV
Dated: October 16, 2012
Received: October 17, 2012

Dear Ms. Germain-Kolawole:

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 -S

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): K122180

Device Name: HIGH FLOW INSUFFLATION UNIT UHI-4

Indications For Use:

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This instrument is intended 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.

This instrument is used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment.

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)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122180