January 13, 2025

Olympus Medical Systems Corporation
% Teffany Hutto
Regulatory Affairs Project Manager
Olympus Corporation of the Americas
800 West Park Drive
Westborough, MA 01581

Re: K243527
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, FCX
Dated: November 15, 2024
Received: November 14, 2024

Dear Teffany Hutto:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243527

Device Name
High Flow Insufflation Unit (UHI-4)

Indications for Use *(Describe)*

The UHI-4 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 CO2 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

1. General Information

Date Prepared: January 8, 2025

510(K) submitter: **Olympus Medical Systems Corporation**
2951 Ishikawa-cho, Hachioji-shi, Tokyo Japan 192-8507
Contact: Shinichiro Kawachi
Email: shinichiro.kawachi@olympus.com

2. Device Information

Device Name: High Flow Insufflation Unit: (UHI-4)
Model Name: Olympus High Flow Insufflation unit (UHI-4)
Common Name: Insufflator, Laparoscopic
Classification: 884.1730 – Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF – Insufflator, Laparoscopic
OSV - Insufflator, endoscopic vessel harvesting
FCX - Insufflator, automatic carbon-dioxide for endoscope
Device Panel: Obstetrics/Gynecology

3. Predicate Device Information

Device Name	510(k) Submitter	510(k) Number
High Flow Insufflation Unit	Olympus Medical Systems	K122180

4. Device Description

The subject device, UHI-4, is intended to insufflate the abdominal cavity, and provides automatic suction and smoke evacuation to facilitate laparoscopic observation, diagnosis and treatment, and for controlled CO2 insufflation to create a cavity along the saphenous vein and/or radial artery to facilitate observation during an endoscopic vessel harvesting procedure. The subject device is also used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment.

The subject UHI-4 has the following system functions which are existing features/functions of the predicate device and are not new feature/function.

- Cavity mode
- Adjustment of the cavity pressure
- Adjustment of the gas flow rate
- Display mode

- Relief mode
- Smoke evacuation
- Automatic smoke evacuation
- Pressure sensor failure detection
- Excessive pressure alarm & alarm delay setting

The subject device has the same technological characteristics and design as the applicable predicate devices. There have been no modifications to the device hardware design including performance specifications and physical design requirements, materials, sterilization, shelf life, reprocessing, or packaging.

The only difference between the subject device and the predicate device is the device software, and there are modifications for two existing software functions: "Pressure sensor failure detection" and "Alarm delay setting".

5. Indications for Use

The UHI-4 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 CO2 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. Predicate Comparison

The subject device does not have different indications for use as compared to the predicate device.

Item	Subject Device UHI-4 K243527	Predicate Device UHI-4 K122180	Comments on Difference
Manufacturer	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	Same as the predicate device
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	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	Same as the predicate device

	during an endoscopic vessel harvesting procedure. This instrument is used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment.	during an endoscopic vessel harvesting procedure. This instrument is used to insufflate the colon to facilitate endoscopic observation, diagnosis and treatment.	
Single-Use/Reuse	Reusable	Reusable	Same as the predicate device
Duration and type of contact	Indirect patient contact by CO_2 gas	Indirect patient contact by CO_2 gas	Same as the predicate device
Distension Medium	CO_2 gas	CO_2 gas	Same as the predicate device
Insufflation Modes	Normal Cavity mode Small Cavity mode	Normal Cavity mode Small Cavity mode	Same as the predicate device
Maximum Flow Rate	Small cavity mode: 10 LPM Normal cavity mode: 45 LPM	Small cavity mode: 10 LPM Normal cavity mode: 45 LPM	Same as the predicate device
Maximum Set Pressure	Small cavity mode: 15 mmHg Normal cavity mode: 25 mmHg	Small cavity mode: 15 mmHg Normal cavity mode: 25 mmHg	Same as the predicate device
Cavity pressure control	When cavity pressure reaches the set pressure level, insufflation will stop. When cavity pressure drops below the set pressure level, insufflation will start again.	When cavity pressure reaches the set pressure level, insufflation will stop. When cavity pressure drops below the set pressure level, insufflation will start again.	Same as the predicate device
Key Safety Features	• Overpressure protection • Tube obstruction • Initial flow rate setting • Supply pressure indications • Monitoring of the volume of gas delivered • Initial cavity mode setting	• Overpressure protection • Tube obstruction • Initial flow rate setting • Supply pressure indications • Monitoring of the volume of gas delivered • Initial cavity mode setting	Same as the predicate device
Filter	End user set the filter. Pore size:≦0.2μm	End user set the filter. Pore size:≦0.2μm	Same as the predicate device
Reprocessing method	End user clearing by wiping with the cloth moisturized with detergent and/or disinfectant.	End user clearing by wiping with the cloth moisturized with detergent and/or disinfectant.	Same as the predicate device

This 510(k) application is to request clearance for a change to the software that controls the insufflation function and warning function to ensure that there is no over insufflation of the abdominal cavity.

7. Non-Clinical/Clinical Tests Summary and Conclusion

As there were no changes to the device design or principles of operation, nonclinical bench testing, animal, testing, or clinical testing were not performed.

Non-clinical testing from the applicant's own predicate (K122180) was leveraged in support of substantial equivalence for the following areas:

- Intended Use / Indications for Use
- Principle of Operation
- Device Design
- Materials
- Electrical Safety
- Human Factors

Software and Cybersecurity testing and documentation were provided to ensure the device's safety, performance, and protection against cybersecurity risks.

- **Software Testing**: Validated that the software meets performance requirements, operates as intended under normal and abnormal conditions, and adheres to FDA guidance for software validation. This testing confirms the reliability of the software in supporting the device's functions without errors or failures that could impact patient safety.
- **Cybersecurity Testing**: Evaluated the device's resilience to cyber threats, including mechanisms to protect against unauthorized access, data tampering, and system vulnerabilities. The documentation included risk assessments, secure update mechanisms, and compliance with relevant industry standards (e.g., CVSS framework). These measures ensure that the device can operate securely in clinical environments, safeguarding patient information and critical device functions.

The following bench tests were conducted to evaluate the performance of the device and ensure its safety and functionality under expected and abnormal conditions:

1. **Overpressure Testing**:
   This test was performed to confirm that the device can withstand pressure beyond its intended operating range without failure. Overpressure testing ensures that the device maintains structural integrity and does not pose risks of leaks, malfunction, or harm to patients or operators under high-pressure scenarios.
2. **Tube Obstruction Testing**:
   Tube obstruction testing evaluates the device's ability to detect and manage blockages in the tubing system. This test is critical to verify that the device can identify an obstruction and respond appropriately to prevent adverse events, such as inadequate suction or gas flow, which could compromise patient safety.
3. **CO_2 Suction Control Testing**:
   This test was conducted to validate the accuracy and reliability of the device's CO_2 suction control mechanism. It ensures that the device can appropriately regulate CO_2

removal, which is essential for maintaining clinical effectiveness, reducing overpressures, and preventing potential complications during procedures.

4. **Hardware Abnormality Testing**:
   This test assesses how the device responds to hardware faults or abnormalities, such as component failures or power disruptions. Testing the device's performance under abnormal conditions ensures that safety mechanisms are in place to detect and mitigate failures, mitigating risks to patients or operators.
5. **Communication of Failure Detail Testing**:
   This test verifies that the device can effectively communicate failure conditions or malfunctions to the user through appropriate error messages or alarms. Clear and accurate communication of failures ensures that users are aware of any issues and can take prompt corrective action to maintain safe and effective operation of the device.

8. Conclusion

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the UHI-4 system does not raise different questions of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.