March 18, 2025

Olympus Medical Systems Corp.
% Roshana Ahmed
Regulatory Affairs Consultant
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K243807
Trade/Device Name: Single Use Retrieval Basket V FG-V421PR/V422PR/V431P/V432P
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: LQR, OCZ
Dated: February 27, 2025
Received: February 27, 2025

Dear Roshana Ahmed:

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.

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,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243807

Device Name

Single Use Retrieval Basket V FG-V421PR/V422PR/V431P/V432P

Indications for Use *(Describe)*

The Single Use Retrieval Basket V FG-V421PR/FG-V422PR/FG-V431P/FG-V432P are intended to be used to retrieve stones from the biliary tract in combination with an endoscope.

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.

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510(k) Summary

I. Submitter

Olympus Medical Systems Corp.
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Contact Person: Seiko Yunoki, Manager, Endotherapy Product, RA TSD
Phone: +81-42-642-2111

Date Prepared: March 3, 2025

II. Device

Device Proprietary Name	Single Use Retrieval Basket V FG-V421PR/V422PR/V431P/V432P
Common or Usual Name	Biliary catheter and accessories
Classification Name	Dislodger, Stone, Biliary
Regulation Number	876.5010
Product Code	LQR, OCZ
Device Classification	2

III. Predicate Device

Substantial equivalence is claimed to the following device:

- Single Use Retrieval Nitinol Basket V, K170811, Olympus Medical Systems Corp.

The following device is cited as a reference device:

- Memory Baskets, K171969, Wilson-Cook Medical Inc.

IV. Device Description

The Single Use Retrieval Basket V Series is comprised of four (4), sterile, single-use, retrieval baskets designed to retrieve stones from the biliary tract. The retrieval baskets, manufactured from stainless steel, are provided as an 8-wire or 4-wire type.

Each device has two sections: the handle and the insertion portion. The grip of the handle is used to control and operate the retrieval basket. The insertion portion, consisting of the sheath and the retrieval basket, is introduced into the biliary tract through an endoscope.

The subject devices are intended to be used with Olympus endoscopes featuring a working length of less than 1400 mm (model: TJF) and a channel inner diameter of Ø 4.2 mm. The Olympus Lithotriptor (model BML-110A-1 or BML-610A) may be used in case of an emergency.

Legally marketed Olympus guidewires (outer diameter Ø 0.89 mm) may be used with the Single Use Retrieval Basket V FG-V431P and FG-V432P models.

V. Indications for Use

The Single Use Retrieval Basket V FG-V421PR/FG-V422PR/FG-V431P/FG-V432P are intended to be used to retrieve stones from the biliary tract in combination with an endoscope.

VI. Comparison of Technological Characteristics

The subject device has the same intended use as the predicate device.

A comparison of the subject and predicate device technological characteristics is provided below.

	Subject Device **Single Use Retrieval Basket V Series**	**Predicate Device** **Single Use Retrieval Nitinol Basket**	**Analysis**
Indications for use	The Single Use Retrieval Basket V FG-V421PR/V422PR/V431P/V432P are intended to be used to retrieve stones from the biliary tract in combination with an endoscope.	The instrument has been designed to be used with Olympus endoscopes to retrieve stones from the biliary tract.	Substantially equivalent
Models	FG-V421PR FG-V422PR FG-V431P	FG-V451P	-

	FG-V432P		
Working Length	1900 mm	1900 mm	Identical
Opening Width	20 mm 22 mm	20 mm	Substantially equivalent
Maximum Insertion Portion Diameter	Ø 2.4 mm Ø 2.9 mm	Ø 2.9 mm	Substantially equivalent
Minimum Working Channel Size	Ø 4.2 mm	Ø 3.7 mm	Substantially equivalent
Retrieval Basket Configuration Type	8 wire type 4 wire type	8 wire spiral type	Substantially equivalent
Basket Function	Rotatable Distal Wire-Guided	Distal Wire-Guided	Substantially equivalent
Basket Wire Material	Stainless steel	Nitinol	Substantially equivalent
Biocompatibility	ISO 10993-1	ISO 10993-1	Identical
Sterile	Yes, Ethylene oxide	Yes, Ethylene oxide	Identical
Single Use	Yes	Yes	Identical

The subject device and predicate devices are sterile, single use, retrieval baskets with a working length of 1900 mm which are used with compatible Olympus endoscopes.

The subject device models FG-V421PR and FG-V431P are identical to the predicate device with respect to opening width, retrieval basket configuration type. The subject device models FG-V431P and FG-V432P are identical to the predicate device with respect to the maximum insertion portion diameter, and basket function.

The subject and predicate devices differ as follows:

- Models FG-V422PR and FG-V432P feature an opening width of 22 mm and a 4 wire type retrieval basket configuration
- Models FG-V421PR and FG-V422PR feature a maximum insertion portion diameter of 2.4 mm, a minimum working channel size of 4.2 mm, and a rotatable basket,
- The shape of the retrieval basket
- Basket wire material

The differences in basket function (introduction of rotatable baskets), opening width (introduction of 22 mm opening width), maximum insertion portion diameter (introduction of 2.4 mm diameter), minimum working channel size (introduction of 4.2 mm), basket wire shape, configuration type (introduction of 4 wire type) and material of construction do not raise

different questions of safety or effectiveness when comparing the subject device to the predicate device. These differences are addressed through bench testing and biocompatibility testing of the subject device and predicate and reference devices. Testing on a reference device supports the difference in basket function (introduction of rotatable baskets).

VII. Performance Data

The following performance data were provided to demonstrate substantial equivalence:

- Biocompatibility testing per ISO 10993-1:2018 including cytotoxicity, sensitization, irritation, acute systemic toxicity, and material mediated pyrogenicity.
- Sterilization validation per ISO 11135:2014.
- Packaging validation and shelf life testing in accordance with ISO 11607-1:2019 and ASTM F1980-21.
- Mechanical testing to verify device performance:
  - Insertion / Withdrawal
  - Open / Close Basket
  - Dimensional verification
  - Grasping Basket Effective Test
  - Grasping Basket Effective Test
  - Attachment / Detachment of Hook
  - Injecting Fluid
  - Strength of Junction

Animal study data and clinical study data were not required to demonstrate substantial equivalence.

VIII. Conclusion

The Single Use Retrieval Basket V Series models have the same intended use, and principles of operation as the predicate devices. Non-clinical testing demonstrates that the slight differences in device design do not alter the safety, efficacy, or performance of the subject devices when compared to the predicate devices.

The technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness when compared to the predicate devices. The data presented within this submission supports substantial equivalence of the Single Use Retrieval Basket V Series to the identified predicate devices.