May 27, 2025

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

Re: K250573
Trade/Device Name: Single Use Cannula V PR-V223Q/V414Q/V416Q/V418Q/V420Q/ V427Q/ V434Q/V435Q;
Single Use 2-Lumen Cannula V PR-V614M
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODD
Dated: February 26, 2025
Received: February 26, 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
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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.

510(k) Number *(if known)*
K250573

Device Name
Single Use Cannula V PR-V223Q/V414Q/V416Q/V418Q/V420Q/V427Q/V434Q/V435Q;
Single Use 2-Lumen Cannula V PR-V614M

Indications for Use *(Describe)*
The Single Use Cannula V PR-V223Q/V414Q/V416Q/V418Q/V420Q/V427Q/V434Q/V435Q are intended to be used to inject contrast medium in the biliary or pancreatic duct in combination with an endoscope.

The Single Use 2-Lumen Cannula V PR-V614M is intended to be used to inject contrast medium in the biliary or pancreatic duct 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 Corporation
2951 Ishikawa-cho
Hachiochi-shi
Tokyo 192-8507
Japan

Contact Person: Seiko Yunoki
Phone: +81 42-642-2111

Date Prepared: February 10, 2025

II. Device

Device Proprietary Name	Single Use Cannula V PR-V223Q/ V414Q/ V416Q/ V418Q/ V420Q/ V427Q/ V434Q/ V435Q Single Use 2-Lumen Cannula V PR-V614M
Common or Usual Name	ERCP Cannula
Classification Name	Endoscope and accessories
Regulation Number	876.1500
Product Code	ODD
Device Classification	Class II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- ERCP Catheters (ERCP, GT, FD-GT, HRC, and SUC), K171989, Wilson-Cook Medical Inc.

IV. Device Description

The Single Use Cannula V and the Single Use 2-Lumen Cannula V PR Series is comprised of nine (9) sterile, single-use, cannulas designed to inject contrast medium in the biliary or pancreatic duct when used in conjunction with a compatible endoscope.

Each device has two sections: the handle (proximal portion) and the insertion portion. The insertion portion is introduced into the biliary or pancreatic ducts through an endoscope. The distal end of the insertion portion is designed for smooth cannulation of the papilla of Vater or the minor papilla. All models are visible under fluoroscopy and feature a distal marking system.

The Single Use Cannula V and the Single Use 2-Lumen Cannula V PR Series models are to be used with compatible endoscopes.

V. Indications for Use

The Single Use Cannula V PR-V223Q/V414Q/V416Q/V418Q/V420Q/V427Q/V434Q/V435Q are intended to be used to inject contrast medium in the biliary or pancreatic duct in combination with an endoscope.

The Single Use 2-Lumen Cannula V PR-V614M is intended to be used to inject contrast medium in the biliary or pancreatic duct in combination with an endoscope.

VI. Comparison of Technological Characteristics

The Single Use Cannula V and the Single Use 2-Lumen Cannula V PR Series models have the same intended use, and principles of operation as the predicate devices. The subject device and predicate devices are sterile (via EtO), single use, cannulas which are used with compatible endoscopes. The cannulas are offered with and without stylets and fluoro tips and feature the same distal tip diameters as the predicate devices.

The subject and predicate devices differ as follows:

- the subject device cannulas have a larger maximum insertion portion diameter than the predicate devices.
- the working length of the subject device cannulas is shorter than the working length of the predicate devices.

The differences in insertion portion diameter and working length do not raise different questions of safety or effectiveness when comparing the subject device to the predicate device. 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.

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

	Single Use Cannula V and Single Use 2-Lumen Cannula V PR Series **(PR-V223Q, PR-V414Q, PR-V416Q, PR-V418Q, PR-V420Q, PR-V427Q, PR-V434Q, PR-V435Q, PR-V614M)**	**ERCP Catheters** **(Classic ERCP Catheter, Glo-Tip® ERCP Catheter, Fusion® ERCP Catheter with DomeTip®, Haber RAMP™ Catheter, and Soehendra Universal Catheter)**	**Analysis**
510(k) Number	TBD	K171989	N/A
Indications for Use Statement	The Single Use Cannula V PR-V223Q/V414Q/V416Q/ V418Q/ V420Q/V427Q/V434Q/V435Q are intended to be used to inject contrast medium in the biliary or pancreatic duct in combination with an endoscope. The Single Use 2-Lumen Cannula V PR-V614M is intended to be used to inject contrast medium in the biliary or pancreatic duct in combination with an endoscope.	This device is used for endoscopic cannulation of the ductal system. This device is indicated for adult use only.	Substantially equivalent
Models	PR-V223Q PR-V414Q PR-V416Q PR-V418Q PR-V420Q PR-V427Q PR-V434Q PR-V435Q PR-V614M	Huibregtse-Katon® ERCP Catheter Glo-Tip® ERCP Catheter Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands	Substantially equivalent
Distal tip diameter (Fr)	PR-V223Q: 6 Fr PR-V414Q: 4.5 Fr PR-V416Q: 4 Fr PR-V418Q: 3.5 Fr PR-V420Q: 3.5 Fr PR-V427Q: 2.5 Fr PR-V434Q: 4 Fr PR-V435Q: 3.5 Fr PR-V614M: 4.5 Fr	Huibregtse-Katon® ERCP Catheter: • G57289: 5.4Fr Glo-Tip® ERCP Catheter: • G22302 (GT-5-4-3): 3 Fr • G21452(GT1-1-LT): 3.5 Fr • G21500(GT-1-ST): 3.5 Fr • G22093(GT-1): 5.5 Fr • G22621(GT-1-T): 4.5Fr • G22719(GT-1-TE): 4.5 Fr • G21965(GT-1-T-ANG): 4.5 Fr • G22305(GT-1-UT): 4 Fr	Substantially equivalent

		Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands: • G24694: 6Fr	
Maximum insertion portion diameter (mm)	PR-V223Q: ø 2 PR-V414Q/V416Q/V418Q/V420Q/V427Q/V434Q/V435Q: ø 2.1 PR-V614M: ø 2.5	Huibregtse-Katon® ERCP Catheter: • G57289: ø 1.8 Glo-Tip® ERCP Catheter: • G22302 (GT-5-4-3): ø 1.83 • G21452 (GT1-1-LT): ø 1.83 • G21500 (GT-1-ST): ø 1.83 • G22093 (GT-1): ø 1.83 • G22621 (GT-1-T): ø 1.83 • G22719 (GT-1-TE): ø 1.83 • G21965 (GT-1-T-ANG): ø 1.83 • G22305 (GT-1-UT): ø 1.83 Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands: • G24694: ø 2.0	Substantially equivalent
Working length (mm)	PR-V223Q/V414Q/V416Q/V418Q/V420Q/V427Q/V434Q/V435Q: • 1950 PR-V614M • 1700	Huibregtse-Katon® ERCP Catheter: • G57289: 1950 Glo-Tip® ERCP Catheter: • G22302: 2000 • G21452 (long taper): 2000 • G21500 (short taper): 2000 • G22093 (standard): 2000 • G22621 (taper): 2000 • G22719 (taper): 3200 • G21965: 2000 • G22305: 2000 Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands: • G24694: 2000	Substantially equivalent
Stylet and tip design	PR-V223Q • Stylet with ball tip	Huibregtse-Katon® ERCP Catheter: • G57289: With Stylet and Ball tip	Identical

	PR-V414Q/V416Q/V418Q/V420Q/V427Q/V434Q/V435Q: • Stylet with fluoro tip PR-V614M • Fluoro tip	Glo-Tip® ERCP Catheter: • G22302 (GT-5-4-3): With Stylet and Fluoro tip • G21452(GT1-1-LT): With Stylet and Fluoro tip • G21500(GT-1-ST): With Stylet and Fluoro tip • G22093(GT-1): With Stylet and Fluoro tip • G22621(GT-1-T): With Stylet and Fluoro tip • G22719(GT-1-TE): With Stylet and Fluoro tip • G21965(GT-1-T-ANG): With Stylet and Fluoro tip • G22305(GT-1-UT): With Stylet and Fluoro tip Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands: • G24694: With Stylet and Fluoro tip	
Sterilization	Ethylene Oxide	Ethylene Oxide	Identical
Single-Use/ Reusable	Single Use	Single Use	Identical

VII. Performance Data

The following performance data were provided to demonstrate substantial equivalence:

- Biocompatibility testing per ISO 10993-1:2018 including cytotoxicity (ISO 10993-5:2009), sensitization (ISO 10993-10:2021), irritation (ISO 10993-23:2021), acute systemic toxicity (ISO 10993-11:2017), and material mediated pyrogenicity (USP <51>)
- Sterilization validation per ISO 11135:2014
- Ethylene oxide residuals per ISO 10993-7:2008
- Packaging validation and shelf life testing in accordance with ISO 11607-1:2019 and ASTM F1980-21
- Mechanical testing and comparative testing to verify device performance:
    - Insertion force/ Withdrawal force
    - Insertion w/ Stylet
    - Attachment and detachment of the hook
    - Contrast medium infusion

- Connection strength
- Visibility
- Human Factors Testing

Clinical data is not required to demonstrate substantial equivalence.

VIII. Conclusion

The non-clinical data demonstrate that the subject device is as safe, as effective, and performs as well as or better than the identified predicate device. Therefore, it is concluded that the Single Use Cannula V and the Single Use 2-Lumen Cannula V PR Series are substantially equivalent to the identified predicate device.