October 17, 2025

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

Re: K250945
Trade/Device Name: Single Use Preloaded Sphincterotome V (Distal Wire Guided) (KD-VC600 Series); Single Use Sphincterotome V (Distal Wire Guided) (KD-VC400 Series); Single Use 3-Lumen Sphincterotome (KD-V Series); Disposable Triple Lumen Sphincterotome (KD Series)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: September 18, 2025
Received: September 19, 2025

Dear Jillian Connery:

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
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250945

Please provide the device trade name(s).

Single Use Preloaded Sphincterotome V (Distal Wireguided) (KD-VC600 Series);
Single Use Sphincterotome V (Distal Wireguided) (KD-VC400 Series);
Single Use 3-Lumen Sphincterotome (KD-V Series);
DISPOSABLE TRIPLE LUMEN SPHINCTEROTOME (KD Series)

Please provide your Indications for Use below.

The Single Use Preloaded Sphincterotome V (Distal Wireguided) KD-VC631Q Series are intended to be used for papillotomy using high-frequency current in combination with an endoscope. The preloaded guidewire is used for guiding and exchanging endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

The Single Use Sphincterotome V (Distal Wireguided) KD-VC411Q/VC431Q/VC433Q Series are intended to be used for papillotomy using high-frequency current in combination with an endoscope.

The Single Use 3-Lumen Sphincterotome V KD-V411M/V431M Series is intended to be used for papillotomy using high-frequency current in combination with an endoscope and guidewire.

The DISPOSABLE TRIPLE LUMEN SPHINCTEROTOME KD-411Q/431Q Series is intended to be used for papillotomy using high-frequency current in combination with an endoscope.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K250945

510(k) Summary

Prepared on: 2025-09-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Olympus Medical Systems Corp.
Applicant Address	2951 Ishikawa-cho Hachiochi-shi Tokyo 192-8507 Japan
Applicant Contact Telephone	+81 42-642-2111
Applicant Contact	Ms. Seiko Yunoki
Applicant Contact Email	seiko.yunoki@olympus.com
Correspondent Name	Olympus Corporation of the Americas
Correspondent Address	800 West Park Drive Westborough MA 01581 United States
Correspondent Contact Telephone	614-817-2029
Correspondent Contact	Ms. Jillian Connery
Correspondent Contact Email	Jillian.Connery@olympus.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Single Use Preloaded Sphincterotome V (Distal Wireguided) (KD-VC600 Series); Single Use Sphincterotome V (Distal Wireguided) (KD-VC400 Series); Single Use 3-Lumen Sphincterotome (KD-V Series); DISPOSABLE TRIPLE LUMEN SPHINCTEROTOME (KD Series)
Common Name	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)
Classification Name	Endoscopic electrosurgical unit and accessories
Regulation Number	876.4300
Product Code(s)	KNS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141991	Single Use Sphincterotome V, Single Use Preloaded Sphincterotome V (Distal Wireguided)	KNS

Device Description Summary

21 CFR 807.92(a)(4)

The Single Use Sphincterotome KD-VC, KD-V, and KD Series consists of the following devices:
- Single Use Preloaded Sphincterotome V (Distal Wireguided) KD-VC600 Series (aka CleverCut3V)
- Single Use Sphincterotome V (Distal Wireguided) KD-VC400 Series (aka CleverCut3V)
- Single Use 3-Lumen Sphincterotome V KD-V Series (aka CleverCut3V)
- DISPOSABLE TRIPLE LUMEN SPHINCTEROTOME KD Series (aka FlowCut)

The subject devices have separate lumens for guidewire, cutting wire and injection of contrast medium for papillotomy. The knives are pre-curved and have a tapered tip to facilitate insertion into the papilla of Vater. The insertion portion of the KD-V, and KD-VC Series have a V-marking, which the relative insertion length into the endoscope can be confirmed by the positional relationship between the V-marking and the biopsy valve of the endoscope and feature an integrated C-Hook to attach to the endoscope. The distal end of the sphincterotome is coated with CleverCut Coating®, Olympus' PFA (perfluoroalkoxy) coating designed to prevent thermal injury to non-target tissue while cutting the papilla of Vater. The KD-VC600 Series offers models that are preloaded with VISIGLIDE guidewires.

The subject devices are provided to the user sterilized by ethylene oxide and intended for single use only.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The DISPOSABLE TRIPLE LUMEN SPHINCTEROTOME KD-411Q/431Q Series is intended to be used for papillotomy using high-frequency current in combination with an endoscope

The Single Use 3-Lumen Sphincterotome V KD-V411M/V431M Series is intended to be used for papillotomy using high-frequency current in combination with an endoscope and guidewire.

The Single Use Sphincterotome V (Distal Wireguided) KD-VC411Q/VC431Q/VC433Q Series are intended to be used for papillotomy using high-frequency current in combination with an endoscope.

The Single Use Preloaded Sphincterotome V (Distal Wireguided) KD-VC631Q Series are intended to be used for papillotomy using high-frequency current in combination with an endoscope. The preloaded guidewire is used for guiding and exchanging endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the same intended use as the predicate device. The devices are intended to be used for papillotomy using high-frequency current in combination with an endoscope and guidewire. The preloaded guidewire is used for guiding and exchanging endoscopic accessories for biliary duct, including but not limited to the common bile, cystic, pancreatic and right and left hepatic ducts.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device shares the same materials, operates on the same principles and has similar dimensional characteristics as the predicate device. Minor dimensional differences from the predicate include variants with a shorter working length and shorter knife tip length, and compatibility with additional size guidewires. The subject devices are compatible to endoscopes with the same working channel length as the predicate device, and the knife tip length is selected based on physician preference. Comparative bench testing performed demonstrates these dimensional differences do not affect safety or effectiveness of the devices.

The subject device offers models with and without a C-Channel and C-Hook as compared to the predicate, which includes both. The C-Channel and the C-Hook are usability features and not necessary for the device to achieve its intended use; therefore this difference does not raise questions on safety or effectiveness.

The subject device is compatible with additional Olympus generators and compatible A-cords that have been introduced to the market since the predicate was cleared. Compatibility with these generators is verified through electrical safety/EMC testing.

Bench testing, biological safety evaluation, sterilization validation, and shelf-life studies were undertaken on the subject device and predicate device to demonstrate substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing for the subject device was determined based on the device risk assessment and industry recognized standards. Performance bench testing as listed below were conducted to demonstrate the device is safe and effective for its intended use and is substantially equivalent to the predicate device. Bench tests were performed on the Subject Single Use Sphincterotome and Predicate Olympus Single Use Sphincterotome V and Single Use Preloaded Sphincterotome V (Distal Wireguided) cleared under K141991, where applicable for comparative testing. The test results have demonstrated substantial equivalence of the subject device to the predicate device.

Performance testing included the following:
o Dimension of sphincterotome distal end (Knife length)
o Insertion/ withdrawal over the Guidewire
o Insertion/ withdrawal (Mono-rail guidewire technique)

o Attachment/detachment of hook
o Attachment/detachment of the A-cord
o Knife operation (Elevation of the knife)
o Knife operation (Knife direction)
o Papillotomy (resistance of the cutting wire)
o Papillotomy (insulation of the coated portion)
o Contrast Medium Infusion
o Connection strength (between the Tube and the handle)
o Connection strength (between the Tube and the Guidewire Port)
o Visibility test under X-ray

Animal and clinical data was not collected to support substantial equivalence.

Product performance testing of the subject device was conducted, and the device passed all the pre-defined acceptance criteria for each test item demonstrating that design verification has been met. The comparative testing demonstrates the subject device, and the predicate device are substantially equivalent.