



November 25, 2025

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

Re: K252889

Trade/Device Name: Single Use 3-Lumen Needle Knife V (KD-V441M, KD-V451M)

Regulation Number: 21 CFR 876.4300

Regulation Name: Endoscopic Electrosurgical Unit And Accessories

Regulatory Class: Class II

Product Code: KNS

Dated: September 10, 2025

Received: September 10, 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.

K252889

?

Please provide the device trade name(s).

?

Single Use 3-Lumen Needle Knife V (KD-V441M, KD-V451M)

Please provide your Indications for Use below.

?

The Single Use 3-Lumen Needle Knife V KD-V441M/V451M are intended to be used for papillotomy in combination with an endoscope and electro-surgical unit.

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)

?

**Single Use 3-Lumen Needle Knife V KD-V441M, KD-V451M
510(k) SUMMARY****510(k) Summary: K252889****1. COMPANY INFORMATION****• Applicant**

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

• Official Correspondent

Jillian Connery
c/o Olympus Surgical Technologies of the Americas
800 West Park Drive
Westborough, MA 01581
Cell: 614 817-2029
Email: jillian.connery@olympus.com

• Manufacturing Site

AOMORI OLYMPUS CO., LTD.
2-248-1 OKKONOKI
KUROISHI_SHI Aomori, Japan
FDA Establishment Registration #: 3003995201

• Date Prepared: 07-Nov-2025**2. PRODUCT INFORMATION**

- Trade Name: Single Use 3-Lumen Needle Knife V
- Models: KD-V441M, KD-V451M
- Common Name: Endoscopic electro-surgical unit and accessories
- Classification Name: Unit, Electro-surgical, Endoscopic (With Or Without Accessories)
- Product Code: KNS
- Regulation Number: 21 CFR 876.4300
- Regulation Name: Endoscopic Electro-surgical Unit and Accessories
- Device Class: II

3. PREDICATE DEVICE

- Trade Name: Zimmon Needle Knife Papillotome
- Model: PTW-1
- 510(k) Number: K171993

4. REFERENCE DEVICE

- Trade Name: Single Use Sphincterotome V (Distal Wireguided)
- Common Name: CleverCut3V Distal Wireguided
- Model: KD-VC631Q-07201A
- 510(k) Number: K141991

5. DEVICE DESCRIPTION

The Single Use 3-Lumen Needle Knife V (A.K.A NeedleCut 3 V) has 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 knife has 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. The device also features an integrated C-Hook to attach to the endoscope.

The Single Use 3-Lumen Needle Knife V is provided to the user sterilized by ethylene oxide and intended for single use only.

Model KD-451M is coated with CleverCut Coating®, Olympus' PFA (perfluoroalkoxy) coating designed to prevent thermal injury to non-target tissue while cutting the papilla of Vater.

6. INDICATIONS FOR USE

The Single Use 3-Lumen Needle Knife V KD-V441M/V451M are intended to be used for papillotomy in combination with an endoscope and electro-surgical unit.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has minor dimensional differences from the predicate, including a shorter needle length, smaller knife wire diameter, and larger insertion portion diameter. Both devices are compatible with the same guidewire size, and the knife wire diameter matches that of a legally marketed reference device. Comparative benchtop testing—including insertion/withdrawal and cutting performance—demonstrated substantial equivalence. The subject device includes a hook for

usability, which does not affect safety of the device. It is compatible with Olympus generators and cords, while the predicate uses different ESG systems; compatibility was verified through IEC 60601-1 electrical safety testing. Although the predicate's materials and color additives are unspecified, the subject device uses known, biocompatible materials consistent with the reference device. Bench testing, biocompatibility, sterilization validation, and shelf-life studies support substantial equivalence to the predicate device.

8. PERFORMANCE DATA

Performance and human factors testing were 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 3-Lumen Needle Knife V (product codes KD-V441M and KD-V451M), and Predicate Zimmon Needle Knife Papillotome (product code PTW-1), 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, Knife exposure length)
- o Insertion/ withdrawal over the Guidewire
- o Attachment/detachment of hook
- o Attachment/detachment of the A-cord
- o Knife operation
- 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

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. Comparative testing demonstrates the subject device, and the predicate device are substantially equivalent.

9. BIOCOMPATIBILITY

Biocompatibility testing for the Single Use 3-Lumen Needle Knife V (KD-V441M/V451M series) was conducted in accordance with ISO 10993-1:2018 and FDA guidance on the use of ISO 10993 standards. The Single Use 3-Lumen Needle Knife V (KD-V441M/V451M series) is biologically safe and biocompatible for its

intended use and meets the requirements of ISO 10993-1 Biological Evaluation of medical Devices-Part 1 and Guidance for Industry and Food and Drug Administration Staff Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, as verified by an acceptable Biological Risk assessment and the passing results for the biocompatibility testing completed.

10. STERILIZATION AND SHELF LIFE

The Single Use 3-Lumen Needle Knife V KD-V441M, KD-V451M passed the acceptance criteria. The results from the non-clinical performance testing of the aged devices demonstrates the devices are as safe, effective and performs as well as the predicate, for a shelf life of 3 years

11. SUBSTANTIAL EQUIVALENCE

Based on the intended use, technological characteristics, performance testing, and comparison to the predicate device, the Single Use 3-Lumen Needle Knife V KD-V441M, KD-V451M raises no new issues of safety and are substantially equivalent to the predicate device.

12. CONCLUSION

Based on the results of the comparison of the indications for use, technological characteristics, and performance testing of the Subject and Predicate devices, the Subject Single Use 3-Lumen Needle Knife V KD-V441M, KD-V451M raises no new issues of safety and the device is substantially equivalent to the Predicate device.