



October 10, 2025

Olympus Medical Systems Corporation
% Susan Lewandowski
Program Manager, Regulatory Affairs
Olympus Surgical Technologies of America
800 West Park Drive
Westborough, Massachusetts 01581

Re: K250351

Trade/Device Name: Single Use Electrosurgical Knife (KD-612L, KD-612U); Single Use
Electrosurgical Knife (KD-620UR); Single Use Electrosurgical Knife (KD-650L,
KD-650U)

Regulation Number: 21 CFR 876.4300

Regulation Name: Endoscopic Electrosurgical Unit And Accessories

Regulatory Class: Class II

Product Code: KNS

Dated: September 12, 2025

Received: September 12, 2025

Dear Susan Lewandowski:

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,

SIVAKAMI VENKATACHALAM -S

for

Shanil P. Haugen, Ph.D.

Assistant Director

DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices

OHT3: Office of Gastrosrenal, ObGyn,

General Hospital and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250351

Device Name

Single Use Electrosurgical Knife (KD-612L, KD-612U);
Single Use Electrosurgical Knife (KD-620UR);
Single Use Electrosurgical Knife (KD-650L, KD-650U)

Indications for Use (Describe)

The Single Use Electrosurgical Knife KD-612 Series is intended to be used to cut tissue using high-frequency current within the digestive tract in combination with an endoscope and electrosurgical units.

The Single Use Electrosurgical Knife KD-620UR is intended to be used to cut tissue using high-frequency current within the digestive tract in combination with an endoscope and electrosurgical units.

The Single Use Electrosurgical Knife KD-650 Series is intended to be used to cut tissue using high-frequency current within the digestive tract in combination with an endoscope and electrosurgical units.

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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Single Use Electrosurgical Knife KD-612, KD-620UR, and KD-650

510(k) Summary

1. General Information

Date Prepared: September 12, 2025

510(K) submitter: **Olympus Medical Systems Corporation**
2951 Ishikawa-cho, Hachioji-shi, Tokyo Japan 192-8507

Contact: Seiki Yunoki

Correspondent: Olympus Surgical Technologies of America
800 West Park Drive, Westborough, MA 01581

Primary Contact: Susan Lewandowski
Email: susan.lewandowski@olympus.com

2. Device Information

Device Name: Single Use Electrosurgical Knife KD-612
Single Use Electrosurgical Knife KD-620UR
Single Use Electrosurgical Knife KD-650

Model Name: Single Use Electrosurgical Knife KD-612L, KD-612U
Single Use Electrosurgical Knife KD-620UR
Single Use Electrosurgical Knife KD-650L, KD-650U

Common Name: Electrosurgical Knife

Classification: 876.4300 – Endoscopic electrosurgical unit and accessories

Regulatory Class: II

Product Code: KNS

Device Panel: Gastroenterology & Urology

3. Predicate Device Information

Subject Device	Predicate Device	Reference Device
Single Use Electrosurgical Knife KD-612L, KD-612U	Olympus Single Use Electrosurgical Knife KD-611L (K092309)	N/A
Single Use Electrosurgical Knife KD-620UR	Olympus Single Use Electrosurgical Knife KD-625UR (K182408)	Olympus Single Use Electrosurgical Knife KD-620LR (K092309)
Single Use Electrosurgical Knife KD-650L, KD-650U	Olympus Single Use Electrosurgical Knife KD-655L, KD-655U (K171158)	N/A

4. Device Description

The Single Use Electrosurgical Knife was designed to be used with compatible Olympus endoscopes, A-Cord (power cable), and electrosurgical units to cut tissue using high-frequency current within the digestive tract. The subject device is inserted endoscopically into the body cavity and tissue is cut by applying a high frequency current. The subject device is a sterile (EO) single use electrosurgical knife comprised of a handle and an insertion portion. The handle portion consists of the body and the slider. The insertion portion consists of the distal end with one lumen for the stainless-steel cutting knife and the sheath portion. The slider extends the cutting knife from the distal end of the sheath/tube when pushed and retracts the cutting knife into the sheath/tube when the slider is pulled. The Single Use Electrosurgical Knife is available in three different models: KD-612, KD-620UR, and KD-650. The primary difference between the models is the tip shape of the distal end. The subject device has the same technological characteristics and similar design as the applicable predicate device.

5. Indications for Use

The Single Use Electrosurgical Knife KD-612 Series is intended to be used to cut tissue using high frequency current within the digestive tract in combination with an endoscope and electrosurgical units.

The Single Use Electrosurgical Knife KD-620UR is intended to be used to cut tissue using high frequency current within the digestive tract in combination with an endoscope and electrosurgical units.

The Single Use Electrosurgical Knife KD-650 Series is intended to be used to cut tissue using high frequency current within the digestive tract in combination with an endoscope and electrosurgical units.

6. Predicate Comparison

Intended Use

The subject, predicate, and reference devices are intended to be used with endoscopes and electrosurgical units to cut tissue using high-frequency current within the digestive tract.

- The intended use between KD-612U/L and predicate KD-611L is identical.
- The intended use between KD-620UR, predicate KD-625UR, and reference KD-620LR is identical except for the addition of a statement in the predicate's intended use relating to the induction of normal saline into the submucosa. The subject device KD-620UR does not have an irrigation feature, therefore this difference has no impact.
- The intended use between KD-650L/U and predicate KD-655L/U is identical except for the addition of a statement in the predicate's intended use relating to the induction of normal saline into the submucosa. The subject device KD-620UR does not have an irrigation feature, therefore this difference has no impact.

Technological Similarities

- The basic principles of operation are similar between the subject, predicate, and reference devices. All use high frequency current to cut tissue within the digestive tract.
- All are single-use devices provided sterile (Ethylene Oxide) to the end user.

Technological Differences

- Minor dimension differences

The dimensional differences do not impact the safety or effectiveness of the subject device as demonstrated by Performance Testing – Bench.

7. Non-Clinical/Clinical Tests Summary and Conclusion

Olympus performed bench testing to demonstrate substantial equivalence to the predicate device. Test samples were final, finished devices subjected to the full manufacturing process including sterilization.

The following performance bench tests were conducted to demonstrate substantial equivalence between the subject and predicate devices. All test samples passed pre-defined acceptance criteria.

- Insertion into and Withdrawal from an endoscope
- Advancing and Retreating through an endoscope
- Slider Operation
- Cut Digestive Tract Mucosa
- Connection Strength of the Insertion portion and the Handle portion
- Connection Strength of the Working portion
- Histopathological Evaluation for Thermal Denaturation Range
- Human Factors Evaluation

The following testing was also conducted.

- Sterilization/Shelf-life
- Biocompatibility

8. Conclusion

Based on the comparison to the predicate device, intended use, technological characteristics, and performance testing, the Single Use Electrosurgical Knife KD-612, KD-620UR, and KD-650 raise no new issues of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, efficacy, and performance.