

**K250351 Single Use Electrosurgical Knife (KD-612L, KD-612U)**Oct 10, 2025  
245 days to decisionK250351 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k250351/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Feb 7, 2025
Decision date	Oct 10, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Single Use Electrosurgical Knife (KD-620UR); Single Use Electrosurgical Knife (KD-650L, KD-650U)

**APPLICANT**

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Company	<b>Olympus Medical Systems Corporation</b>
Location	Melville, NY, US
Contact	Seiki Yunoki
510(k) history	81 submissions · 81 cleared · 2004-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Olympus Surgical Technologies of America</b>
Contact	Susan Lewandowski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250351/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026