

K250945 Single Use Preloaded Sphincterotome V (Distal Wire Guided) (KD-VC600 Series)

Oct 17, 2025
203 days to decisionK250945 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k250945/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Mar 28, 2025
Decision date	Oct 17, 2025
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Single Use Sphincterotome V (Distal Wire Guided) (KD-VC400 Series); Single Use 3-Lumen Sphincterotome (KD-V Series); Disposable Triple Lumen Sphincterotome (KD Series)

APPLICANT

Company	Olympus Medical Systems Corp.
Location	Hachiochi-Shi, JP
Contact	Seiko Yunoki
Website	https://www.olympus-global.com
510(k) history	101 submissions · 101 cleared · 2012-2026

Olympus Medical Systems Corp. is a global medical device manufacturer headquartered in Hachiochi-Shi, Japan. The company specializes in endoscopic imaging systems and therapeutic devices for minimally invasive procedures. Olympus has received FDA 510(k) clearances from total submissions since 2012. The company's regulatory portfolio is dominated by Gastroenterology & Urology devices, including endoscopes, hemostatic forceps, biopsy instruments, and sphincterotomes. The latest clearance in 2026 reflects continued active development and market engagement. Recent cleared dev...

REGULATORY CONSULTANT

Consulting firm	Olympus Corporation of the Americas
Contact	Jillian Connery

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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Device record: <https://www.510kdatabase.net/k250945/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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