

**K171158 Single Use Electrosurgical knife**Nov 17, 2017  
211 days to decisionK171158 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k171158/>**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	Apr 20, 2017
Decision date	Nov 17, 2017
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Medical Systems Corp.</b>
Location	Hachiochi-Shi, JP
Contact	Toshiyuki Nakajima
Website	<a href="https://www.olympus-global.com">https://www.olympus-global.com</a>
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...