

K123601 SINGLE USE REPOSITIONABLE CLIPApr 29, 2013
159 days to decisionK123601 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k123601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Nov 21, 2012
Decision date	Apr 29, 2013
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Medical Systems Corp.
Location	Hachiochi-Shi, JP
Contact	SHERI L MUSGNUNG
Website	https://www.olympus-global.com
510(k) history	102 submissions · 102 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...
