

**K121564 ENDOSCOPIC ULTRASOUND CENTER EU-Y0006**Oct 16, 2012  
140 days to decisionK121564 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k121564/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	May 29, 2012
Decision date	Oct 16, 2012
Days to decision	140 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	LAURA STORMS-TYLER
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...