

**K111425 OLYMPUS LTF-S190-10, OLUMPUS OTV-S190,  
OLYMPUS CLV-S190**Apr 20, 2012  
333 days to decisionK111425 · Product code: **HET** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k111425/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	May 23, 2011
Decision date	Apr 20, 2012
Days to decision	333 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	SHERI MUSGNUNG
Website	<a href="https://www.olympus-global.com">https://www.olympus-global.com</a>
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...