

**K142680 ENDOCAPSULE SOFTWARE 10**Feb 8, 2015  
142 days to decisionK142680 · Product code: **NEZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k142680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Sep 19, 2014
Decision date	Feb 8, 2015
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary
Other names	ENDOCAPSULE SOFTWARE 10 LIGHT

**APPLICANT**

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Company	<b>Olympus Medical Systems Corp.</b>
Location	Hachiochi-Shi, JP
Contact	Daphney Germain-Kolawole
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...