

**K183053 Olympus Small Intestinal Capsule Endoscope System**Mar 5, 2019  
123 days to decisionK183053 · Product code: **NEZ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k183053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Gastrointestinal, Wireless, Capsule (NEZ)
Date received	Nov 2, 2018
Decision date	Mar 5, 2019
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	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	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...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Olympus Corporation of the Americas</b>
Contact	Daphney Germain-Kolawole

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k183053/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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