

**K220587 Evis Exera III Duodenovideoscope Olympus TJF-Q190V**May 11, 2022  
71 days to decisionK220587 · Product code: FDT · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k220587/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Mar 1, 2022
Decision date	May 11, 2022
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Olympus Medical Systems Corp.</b>
Location	Hachiochi-Shi, JP
Contact	Toshio Nakamura
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...

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Olympus Corporation of the Americas</b>
Contact	Wendy Perreault

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

---

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

Device record: <https://www.510kdatabase.net/k220587/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026