

**K103312 UPD-Y0003**May 12, 2011  
183 days to decisionK103312 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k103312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Nov 10, 2010
Decision date	May 12, 2011
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Olympus Medical Systems Corporation</b>
Location	Melville, NY, US
Contact	STACY KLUESNER
510(k) history	81 submissions · 81 cleared · 2004-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103312/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026