

**K182540 DiLumen Endolumenal Interventional Platform**Oct 30, 2018  
46 days to decisionK182540 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k182540/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Sep 14, 2018
Decision date	Oct 30, 2018
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumendi, LLC</b>
Location	Westport, CT, US
Contact	Dennis Daniels
510(k) history	8 submissions · 8 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182540/> 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 May 26, 2026