

**K210851 DiLumen Endolumenal Interventional Platform  
(DiLumen)**Apr 21, 2021  
30 days to decisionK210851 · Product code: **FDF** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k210851/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Mar 22, 2021
Decision date	Apr 21, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John J. Smith

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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