

K211819 DiLumen C2 and Tool MountOct 22, 2021
133 days to decisionK211819 · Product code: **FDF** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Jun 11, 2021
Decision date	Oct 22, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
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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