

K221452 DiLumen C1, EZ1 and Tool MountFeb 10, 2023
268 days to decisionK221452 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k221452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	May 18, 2022
Decision date	Feb 10, 2023
Days to decision	268 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

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