

K162428 DiLumen Endolumenal Interventional PlatformDec 6, 2016
98 days to decisionK162428 · Product code: **FDF** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k162428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonoscope And Accessories, Flexible/rigid (FDF)
Date received	Aug 30, 2016
Decision date	Dec 6, 2016
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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