FDA 510(k) Premarket Notification

K211819 DiLumen C2 and Tool Mount

CLEARED

Oct 22, 2021
133 days to decision

K211819 · 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