FDA 510(k) Premarket Notification

# K182540 DiLumen Endolumenal Interventional Platform

**CLEARED**

Oct 30, 2018
46 days to decision

K182540 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k182540/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Colonoscope And Accessories, Flexible/rigid (FDF) |
| Date received | Sep 14, 2018 |
| Decision date | Oct 30, 2018 |
| Days to decision | 46 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 |