K183112 DiLumen Endolumenal Interventional Knife (“DiLumen IK™”)

CLEARED

Aug 2, 2019
267 days to decision

K183112 · Product code: **GEI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k183112/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 8, 2018
Decision date	Aug 2, 2019
Days to decision	267 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183112/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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