FDA 510(k) Premarket Notification

K191693 BC-5

CLEARED

Nov 1, 2019
129 days to decision

K191693 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191693/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 2019
Decision date	Nov 1, 2019
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Reveallux, Corp**
Location	Columbus, NE, US
Contact	Justin D Linn
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**FDA 510k Consultants, LLC**
Contact	John Gillespy

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov