

K191693 BC-5Nov 1, 2019
129 days to decisionK191693 · Product code: **GEX** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)

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