

K241407 Splendor X (Alex, Alex2, Nd:YAG, Alex+Nd:YAG)Jun 14, 2024
28 days to decisionK241407 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 17, 2024
Decision date	Jun 14, 2024
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bios S.R.L.
Location	Silver Spring, MD, US
Contact	Martina De Iturbe
510(k) history	14 submissions · 14 cleared · 2005-2024

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241407/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026