

K243445 Splendor X (Alex, Alex2, Nd:YAG, Alex+Nd:YAG)Dec 30, 2024
54 days to decisionK243445 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 6, 2024
Decision date	Dec 30, 2024
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

CLINICAL EVIDENCE - NCT04152707**Clinical Evaluation of Splendor X for Hair Removal**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	44 patients (estimated)
Study sites	2 sites
Condition studied	Hair Remval
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Apr 1, 2023
Sponsor	Lumenis Be Ltd. (Industry)

Primary outcome**Hair reduction**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04152707