

K193500 Stellar M22 for Intense Pulsed Light (IPL) and Laser System

Jan 16, 2020
30 days to decisionK193500 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k193500/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 17, 2019
Decision date	Jan 16, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lumenis, Ltd.
Location	Santa Clara, CA, US
Contact	Shlomit Segman
Website	http://www.lumenis.com/
510(k) history	28 submissions · 27 cleared · 2003-2021

Lumenis, Ltd. is a global leader in energy-based medical device solutions for aesthetic and vision care. The company develops and commercializes innovative laser, intense pulsed light (IPL), and radiofrequency technologies with a manufacturing facility in Santa Clara, California. Lumenis has received FDA 510(k) clearances from total submissions since 2003. The company specializes in General & Plastic Surgery devices, which represent 93% of its regulatory submissions. Its cleared portfolio includes ablative and fractional CO₂ laser systems, IPL platforms, and surgical lase...

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan Kahan

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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Device record: <https://www.510kdatabase.net/k193500/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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