

K162837 Smart Laser Indirect Ophthalmoscope (LIO)Feb 28, 2017
140 days to decisionK162837 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k162837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 11, 2016
Decision date	Feb 28, 2017
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary
Other names	Laser delivery device for Lumenis Novus Spectra Laser System, Lumenis Vision One Laser System, and Lumenis Smart532™ Laser System

APPLICANT

Company	Lumenis, Ltd.
Location	Santa Clara, CA, US
Contact	NAAMA JACOBY
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...