

**K083733 LUME 2 SYSTEM, MODEL GA0005000**May 4, 2009  
139 days to decisionK083733 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k083733/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 16, 2008
Decision date	May 4, 2009
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumenis, Ltd.</b>
Location	Santa Clara, CA, US
Contact	FRANCES HARRISON
Website	<a href="http://www.lumenis.com/">http://www.lumenis.com/</a>
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 CO<sub>2</sub> laser systems, IPL platforms, and surgical lase...

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