

**K130028 RESURFX 1565NM LASER MODULE**Sep 3, 2013  
243 days to decisionK130028 · Product code: **ONG** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k130028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Jan 3, 2013
Decision date	Sep 3, 2013
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumenis, Ltd.</b>
Location	Santa Clara, CA, US
Contact	YORAM LEVY
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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