

**K211979 Lumenis Y&R Laser System**Jun 21, 2022  
361 days to decisionK211979 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k211979/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 2021
Decision date	Jun 21, 2022
Days to decision	361 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumenis, Inc.</b>
Location	Mchenry, IL, US
Contact	Karen Smith
510(k) history	43 submissions · 43 cleared · 1979-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kathy Maynor</b>
Contact	Kathy Maynor

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211979/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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