

**K053628 LIGHTSHEER DUET LASER SYSTEM**Apr 7, 2006  
99 days to decisionK053628 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k053628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 29, 2005
Decision date	Apr 7, 2006
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053628/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 27, 2026