

**K980475 UNIPULSE CO2 SURGICAL LASER SYSTEM**Dec 16, 1998  
313 days to decisionK980475 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k980475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 6, 1998
Decision date	Dec 16, 1998
Days to decision	313 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nidek, Inc.</b>
Location	Mchenry, IL, US
Contact	KEN KATO
510(k) history	77 submissions · 77 cleared · 1983-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980475/> 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 19, 2026