

**K894074 CO2 SURGICAL LASER SYSTEM**Aug 24, 1989  
77 days to decisionK894074 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k894074/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 8, 1989
Decision date	Aug 24, 1989
Days to decision	77 days
Third-party review	No

**APPLICANT**

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Company	<b>Niic U.S.A., Inc.</b>
Location	Redwood City, CA, US
Contact	JUN NISHIMURA
510(k) history	16 submissions · 16 cleared · 1988-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894074/>; 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 July 2, 2026