

**K892359 MODEL NUMBER: IR204 CO2 SURGICAL LASER SYSTEM**Nov 16, 1989  
224 days to decisionK892359 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k892359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 6, 1989
Decision date	Nov 16, 1989
Days to decision	224 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/k892359/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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