

**K971821 UNICA 315 M CO2 SURGICAL LASER SYSTEM**Sep 25, 1997  
132 days to decisionK971821 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k971821/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 16, 1997
Decision date	Sep 25, 1997
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Reliant Technologies, Inc.</b>
Location	Foster City, CA, US
Contact	DAVID W SCHLERF
510(k) history	19 submissions · 19 cleared · 1994-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971821/> 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 June 25, 2026