

**K080638 CLARO**Sep 17, 2008  
195 days to decisionK080638 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k080638/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 6, 2008
Decision date	Sep 17, 2008
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cirs Technology Corporation</b>
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	2 submissions · 2 cleared · 2008-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080638/> 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 21, 2026