

**K081424 AFFIRM CO2 AND AFFIRM CO2 HP**Mar 19, 2009  
303 days to decisionK081424 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k081424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 20, 2008
Decision date	Mar 19, 2009
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cynosure, Inc.</b>
Location	Bedford, MA, US
Contact	GEORGE CHO
510(k) history	98 submissions · 98 cleared · 1992-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081424/> 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 18, 2026