

**K121346 PICOSURE WORKSTATION**Nov 27, 2012  
207 days to decisionK121346 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k121346/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 4, 2012
Decision date	Nov 27, 2012
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cynosure, Inc.</b>
Location	Bedford, MA, US
Contact	IRINA KULINETS
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/k121346/> 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