

**K080382 SELLAS**Sep 24, 2008  
224 days to decisionK080382 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k080382/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 13, 2008
Decision date	Sep 24, 2008
Days to decision	224 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Dinona Co., Ltd.</b>
Location	Littleton, CO, US
Contact	Kevin Walls
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080382/> 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 24, 2026