

**K133915 GALAXY CO2 LASER SYSTEM**Apr 18, 2014  
116 days to decisionK133915 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k133915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 23, 2013
Decision date	Apr 18, 2014
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Beijing Toplaser Technology Co., Ltd.</b>
Location	Chaoyang District, Beijing, CN
Contact	ZHANG XIAOSONG
510(k) history	3 submissions · 3 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133915/> 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 7, 2026