

**K160549 MEDICAL DIODE LASER SYSTEMS**Apr 7, 2017  
403 days to decisionK160549 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k160549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 29, 2016
Decision date	Apr 7, 2017
Days to decision	403 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wuhan Gigaa Optronics Technology Co., Ltd.</b>
Location	#818 Gaoxin Avenue, East Lake Developmen, CN
Contact	NIE XINXING
510(k) history	2 submissions · 2 cleared · 2015-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160549/> 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 1, 2026