

**K152856 Helios III**Jun 2, 2016  
247 days to decisionK152856 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k152856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 29, 2015
Decision date	Jun 2, 2016
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Laseroptek Co., Ltd.</b>
Location	Torrance, CA, US
Contact	HONG CHU
510(k) history	13 submissions · 13 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152856/> 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 May 25, 2026