

**K163009 Litho**Dec 1, 2016  
34 days to decisionK163009 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163009/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 28, 2016
Decision date	Dec 1, 2016
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quanta System Spa</b>
Location	Chelmsford, MA, US
Contact	FRANCESCO DELL'ANTONIO
510(k) history	57 submissions · 57 cleared · 2006-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163009/> 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 2, 2026