

**K180426 Empower H35**Mar 16, 2018  
28 days to decisionK180426 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180426/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 16, 2018
Decision date	Mar 16, 2018
Days to decision	28 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/k180426/> 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 30, 2026