

**K241092 Youlaser PRIME**Oct 10, 2024  
171 days to decisionK241092 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k241092/>**SUBMISSION DETAILS**

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|                       |                                         |
|-----------------------|-----------------------------------------|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Apr 22, 2024                            |
| Decision date         | Oct 10, 2024                            |
| Days to decision      | 171 days                                |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |
| Other names           | Youlaser PRIME CO2; Youlaser PRIME MT   |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Quanta System Spa</b>                |
| Location       | Chelmsford, MA, US                      |
| Contact        | Dario Bandiera                          |
| 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/k241092/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026