

**K983211 CENTAURI**Oct 9, 1998  
25 days to decisionK983211 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k983211/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Sep 14, 1998                            |
| Decision date         | Oct 9, 1998                             |
| Days to decision      | 25 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Premier Laser Systems, Inc.</b>      |
| Location       | Irvine, CA, US                          |
| Contact        | LISA MOJICA                             |
| 510(k) history | 14 submissions · 14 cleared · 1994-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983211/> 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 July 3, 2026