

**K954316 AURORA SURGICAL DIODE LASER SYSTEM  
W/ACCESSORIES**Dec 15, 1995  
91 days to decisionK954316 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k954316/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 15, 1995
Decision date	Dec 15, 1995
Days to decision	91 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954316/> Data sourced from FDA 510(k) public records (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. - Generated July 4, 2026