

**K981379 AURORA**Nov 23, 1998  
221 days to decisionK981379 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k981379/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 16, 1998
Decision date	Nov 23, 1998
Days to decision	221 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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