

**K982113 UMECO OPTIMA 694 RUBY LASER SYSTEM**Sep 30, 1998  
106 days to decisionK982113 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k982113/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 16, 1998
Decision date	Sep 30, 1998
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Umeco, Inc.</b>
Location	Charlestown, MA, US
Contact	IAIN D MILLER
510(k) history	1 submissions · 1 cleared · 1998-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982113/> 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 4, 2026