

**K991634 FOTONA NOVALIS R RUBY LASER SYSTEM**Aug 10, 1999  
90 days to decisionK991634 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k991634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 12, 1999
Decision date	Aug 10, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fotona D.D.</b>
Location	Ljubljana, SI
Contact	MOJCA VALIJAVEC
510(k) history	27 submissions · 27 cleared · 1998-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991634/> 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