

**K001527 FOTONA FIDELIS ER: YAG LASER SYSTEM AND ACCESSORIES**Jul 27, 2000  
72 days to decisionK001527 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k001527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 16, 2000
Decision date	Jul 27, 2000
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fotona D.D.</b>
Location	Ljubljana, SI
Contact	MOJCA VALJAVEC
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/k001527/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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