

**K101306 SP DYNAMIS, SP SPECTRO, XS DYNAMIS, XS SPECTRO, XP DYNAMIS, XP SPECTRO, MODELS M021-4AF/3, M002-2A**Jul 1, 2011  
417 days to decisionK101306 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k101306/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 10, 2010
Decision date	Jul 1, 2011
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fotona D.D.</b>
Location	Ljubljana, SI
Contact	STOJAN TROST
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/k101306/>; 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 June 4, 2026