

**K090126 FOTONA XP ND: YAG LASER SYSTEM FAMILY,
FOTONA XP, XP-2 FOCUS, FOTONA XP CHANGER, MODEL
MOO1-14F, MOO1-14F, MOO1-14F/2,**Jun 29, 2009
159 days to decisionK090126 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k090126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 21, 2009
Decision date	Jun 29, 2009
Days to decision	159 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fotona D.D.
Location	Ljubljana, SI
Contact	STOJAN TROST
510(k) history	27 submissions · 27 cleared · 1998-2015

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