

**K070355 FOTONA FIDELIS III ER:YAG/ND:YAG LASER SYSTEM
FAMILY**Mar 4, 2008
392 days to decisionK070355 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k070355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 6, 2007
Decision date	Mar 4, 2008
Days to decision	392 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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