

K053139 FOTONA QX ND:YAG/KTP LASER SYSTEMFeb 16, 2006
99 days to decisionK053139 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k053139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 9, 2005
Decision date	Feb 16, 2006
Days to decision	99 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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