

K022838 FOTONA DUALIS ER:YAG/KTP LASER SYSTEMNov 25, 2002
90 days to decisionK022838 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k022838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 27, 2002
Decision date	Nov 25, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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