

K011939 FOTONA DUALIS, FOTONA DUALIS PLUSDec 27, 2001
189 days to decisionK011939 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k011939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 21, 2001
Decision date	Dec 27, 2001
Days to decision	189 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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