

K083034 FOTONA XD-2 DIODE LASER SYSTEM, MODEL MD01-2FFeb 4, 2009
117 days to decisionK083034 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k083034/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 10, 2008
Decision date	Feb 4, 2009
Days to decision	117 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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