

K024204 FOTONA FIDELIS PLUS ND:YAG LASER SYSTEMJul 7, 2003
199 days to decisionK024204 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k024204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 20, 2002
Decision date	Jul 7, 2003
Days to decision	199 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k024204/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026