

K093162 FIDELIS PLUS III D, AT FIDELIS D, POWERLASE AT D / FIDELIS PLUS III, AT FIDELIS, POWERLASE AT / FIDELIS ER III D, HT FIDJan 22, 2010
108 days to decisionK093162 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k093162/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 6, 2009
Decision date	Jan 22, 2010
Days to decision	108 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093162/> 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 June 4, 2026