

K143723 SP Dynamis, SP Spectro, XS Dynamis, XP Dynamis, XP Spectro

Apr 9, 2015
101 days to decision

K143723 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k143723/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 29, 2014
Decision date	Apr 9, 2015
Days to decision	101 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.net

Device record: <https://www.510kdatabase.net/k143723/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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