

K182088 XS Dynamis, XP Dynamis, SP Dynamis, XP Spectro, SP Spectro

Oct 31, 2018
90 days to decision

K182088 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k182088/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 2, 2018
Decision date	Oct 31, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fotona D.O.O.
Location	Ljubljana, SI
Contact	Marko Berdajs
510(k) history	16 submissions · 16 cleared · 2017-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k182088/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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