

K202991 Fotona XPulse Pro Laser PlatformJun 22, 2021
265 days to decisionK202991 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2020
Decision date	Jun 22, 2021
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	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.netDevice record: <https://www.510kdatabase.net/k202991/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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