FDA 510(k) Premarket Notification

CLEARED

K221712 Fotona XPulse Laser System Family (XPulse 1064 nm, XPulse 810 nm, XPulse 980 nm)

Oct 12, 2022
121 days to decision

K221712 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221712/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 13, 2022
Decision date	Oct 12, 2022
Days to decision	121 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.net
Device record: https://www.510kdatabase.net/k221712/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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