FDA 510(k) Premarket Notification

K202991 Fotona XPulse Pro Laser Platform

CLEARED

Jun 22, 2021
265 days to decision

K202991 · Product code: **GEX** · General & Plastic Surgery
Source: 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