

K242202 LightWalker Laser System FamilyAug 23, 2024
28 days to decisionK242202 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 26, 2024
Decision date	Aug 23, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242202/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026