

**K202985 LightWalker Laser System Family**Mar 19, 2021  
170 days to decisionK202985 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202985/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2020
Decision date	Mar 19, 2021
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Fotona D.O.O.</b>
Location	Ljubljana, SI
Contact	Pucer Anja
510(k) history	16 submissions · 16 cleared · 2017-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202985/> 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 26, 2026