

**K193661 LightWalker Laser System Family**Mar 25, 2020  
86 days to decisionK193661 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193661/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 30, 2019
Decision date	Mar 25, 2020
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193661/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026