

**K243630 Medical Laser System Incanto / Evoline Platinum  
/Evoline**Mar 21, 2025  
116 days to decisionK243630 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243630/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 25, 2024
Decision date	Mar 21, 2025
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Solar LS Cjsc</b>
Location	Minsk, BY
Contact	Dmitry Kiselevich
510(k) history	1 submissions · 1 cleared · 2025-2025

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243630/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026