

**K261214 PICO SHINING (PICO-K)**May 11, 2026  
27 days to decisionK261214 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k261214/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 14, 2026
Decision date	May 11, 2026
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PICOFY)

**APPLICANT**

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Company	<b>Speclipse, Inc.</b>
Location	Gyeonggi-Do, KR
Contact	HeaJung Kim
510(k) history	3 submissions · 3 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k261214/> 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 June 5, 2026