

K253342 PICO-KDec 24, 2025
85 days to decisionK253342 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2025
Decision date	Dec 24, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Specclipse, Inc.
Location	Gyeonggi-Do, KR
Contact	Myung Seo Park
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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