

K252599 Diode Laser Therapy Systems (WLA-02)Feb 24, 2026
190 days to decisionK252599 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k252599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 18, 2025
Decision date	Feb 24, 2026
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wingderm Electro-Optics , Ltd.
Location	Beijing, CN
Contact	Juan Zhou
510(k) history	3 submissions · 3 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	Suzhou Device Innovation Medical Consulting Co., Ltd.
Contact	Mike Gu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252599/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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