

K243037 Diode Laser System model Dawn-SDec 26, 2024
90 days to decisionK243037 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 27, 2024
Decision date	Dec 26, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Wonderful Opto-Electrics Tech.Co.,Ltd
Location	Shanghai, CN
Contact	Lily Zhou
510(k) history	6 submissions · 6 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243037/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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