

**K251801 Diode laser device (BM091)**Aug 8, 2025  
57 days to decisionK251801 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k251801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 12, 2025
Decision date	Aug 8, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hebei Newangie Technology Co., Ltd.</b>
Location	Shijiazhuang, CN
Contact	Ning Wang
510(k) history	2 submissions · 2 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Believe-Med Technology Service Co., Ltd.</b>
Contact	Wang Ray

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

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