FDA 510(k) Premarket Notification

K251801 Diode laser device (BM091)

CLEARED

Aug 8, 2025
57 days to decision

K251801 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251801/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Beijing Believe-Med Technology Service Co., Ltd.**
Contact	Wang Ray

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