FDA 510(k) Premarket Notification

K251457 Diode laser therapy device (VADER)

CLEARED

Sep 3, 2025
114 days to decision

K251457 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251457/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 12, 2025
Decision date	Sep 3, 2025
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Superlaser Technology Co., Ltd.**
Location	Xihongmen Town, Daxing District, Beijing, CN
Contact	Shuang Shi
510(k) history	5 submissions · 5 cleared · 2019-2025

REGULATORY CONSULTANT

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

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