FDA 510(k) Premarket Notification

CLEARED

K262070 Diode Laser Therapy Systems (DL612A)

Aug 19, 2026
58 days to decision

K262070 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k262070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 22, 2026
Decision date	Aug 19, 2026
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hebei Zollvan Medical Technology Co., Ltd.**
Location	Baoding, CN
Contact	Zhichao Ma
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Tianjin Xinnuocheng Medical Technology Co., Ltd.**
Contact	Liya Meng

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