FDA 510(k) Premarket Notification

CLEARED

K261841 Q Switched Nd:YAG Laser machine (QLQW-01)

Aug 11, 2026
69 days to decision

K261841 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k261841/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 3, 2026
Decision date	Aug 11, 2026
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beijing Nubway S&T Co., Ltd.**
Location	Beijing, CN
Contact	Xiting Fan
510(k) history	5 submissions · 5 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**Tianjin Xinnuocheng Medical Technology Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov