FDA 510(k) Premarket Notification

CLEARED

K242943 Q Switched Nd:YAG Laser machine (QNHF-01)

Mar 3, 2025
159 days to decision

K242943 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 25, 2024
Decision date	Mar 3, 2025
Days to decision	159 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	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

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