

K242941 CO2 Laser Therapy Systems (SHE-LSP003-1)Jan 27, 2025
124 days to decisionK242941 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 25, 2024
Decision date	Jan 27, 2025
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beijing Sano Laser S&T Development Co.,Ltd
Location	Beijing, CN
Contact	Li Zhengrong
510(k) history	5 submissions · 5 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Microkn Medical Technology Service (Shanghai)Co.,Ltd Company
Contact	Owen He

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

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