

K250183 CO2 Laser System (CO2 Laser SST-L23)Apr 24, 2025
92 days to decisionK250183 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 22, 2025
Decision date	Apr 24, 2025
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhuozhou Summer Star Technologies Co., Ltd.
Location	Zhuozhou, CN
Contact	Lei Yan
510(k) history	1 submissions · 1 cleared · 2025-2025

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

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