

**K252519 CO2 Laser Therapy System (K106)**Nov 7, 2025  
88 days to decisionK252519 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 11, 2025
Decision date	Nov 7, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hebei Keylaser Sci-Tech Co.,Ltd</b>
Location	Baoding, CN
Contact	Zhen Yang
510(k) history	3 submissions · 3 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Beijing Believe-Med Technology Service Co., Ltd.</b>
Contact	Ray Wang

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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