

**K240611 IVYLASER Diode laser hair removal system (IVY-HR-Alloy)**Jun 20, 2024  
107 days to decisionK240611 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k240611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 5, 2024
Decision date	Jun 20, 2024
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ivylaser (Beijing) Technology Co.,Ltd</b>
Location	Beijing, CN
Contact	Yuan Xiujuan
510(k) history	3 submissions · 3 cleared · 2023-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Microkn Medical Technology Service (Shanghai) Co., Ltd.</b>
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)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240611/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026