

**K231548 Medical Diode Laser, Model S1Pro**Aug 3, 2023  
65 days to decisionK231548 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231548/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 30, 2023
Decision date	Aug 3, 2023
Days to decision	65 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Wuhan Pioon Technology Co., Ltd.</b>
Location	Wuhan, CN
Contact	Feng Zhang
510(k) history	7 submissions · 7 cleared · 2023-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>leanRAQA</b>
Contact	Valerie Followell

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231548/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026