

**K250041 Medical Picosecond ND: YAG Laser System (PZ-6)**May 14, 2025  
126 days to decisionK250041 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250041/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Jan 8, 2025                             |
| Decision date         | May 14, 2025                            |
| Days to decision      | 126 days                                |
| Third-party review    | No                                      |
| Combination product   | No                                      |
| PCCP authorized       | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Zhengzhou PZ Laser Slim Technology Co., Ltd.</b> |
| Location       | High-Tech Development Zone, Zhengzhou, CN           |
| Contact        | Junmei Li   |
| 510(k) history | 6 submissions · 6 cleared · 2018-2025               |

**REGULATORY CONSULTANT**

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|-----------------|---|
| Consulting firm | <b>Shanghai Truthful Information Technology Co., Ltd.</b> |
| Contact         | Boyle Wang  |

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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250041/> 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 14, 2026