

K213225 Diode Laser System GP900A8, Diode Laser System GP900Q8Dec 22, 2021
84 days to decisionK213225 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213225/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Sep 29, 2021 |
| Decision date | Dec 22, 2021 |
| Days to decision | 84 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Shenzhen Gsd Tech Co., Ltd. |
| Location | Shanghai, CN |
| Contact | Huifang Yao |
| 510(k) history | 7 submissions · 7 cleared · 2009-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213225/> 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