

K193477 Nd: YAG Laser Therapy SystemsJun 24, 2020
191 days to decisionK193477 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193477/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Dec 16, 2019 |
| Decision date | Jun 24, 2020 |
| Days to decision | 191 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Beijing Kes Biology Technology Co., Ltd. |
| Location | Shanghai, CN |
| Contact | Wei Meng Meng |
| 510(k) history | 3 submissions · 3 cleared · 2013-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193477/> 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 27, 2026