

K023881 PROFILE 1064 LASER SYSTEMJun 13, 2003
204 days to decisionK023881 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k023881/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Nov 21, 2002 |
| Decision date | Jun 13, 2003 |
| Days to decision | 204 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sciton, Inc |
| Location | Palo Alto, CA, US |
| Contact | JAY M PATEL |
| 510(k) history | 23 submissions · 23 cleared · 2000-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023881/> 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 31, 2026