

K133364 PICOSURE WORKSTATIONJul 22, 2014
263 days to decisionK133364 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k133364/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Nov 1, 2013 |
| Decision date | Jul 22, 2014 |
| Days to decision | 263 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Cynosure, Inc. |
| Location | Bedford, MA, US |
| Contact | Connie Hoy |
| 510(k) history | 98 submissions · 98 cleared · 1992-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133364/> 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 June 18, 2026