

K101601 AFFIRM DO DIODE LASERSep 23, 2010
107 days to decisionK101601 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k101601/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jun 8, 2010 |
| Decision date | Sep 23, 2010 |
| Days to decision | 107 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101601/> 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