

K112253 CERALAS 147NM DIODE LASER SYSTEMSep 20, 2011
46 days to decisionK112253 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k112253/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Aug 5, 2011 |
| Decision date | Sep 20, 2011 |
| Days to decision | 46 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biolitec, Inc. |
| Location | East Longmeadow, MA, US |
| Contact | HARRY HAYES |
| 510(k) history | 28 submissions · 28 cleared · 2001-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112253/> 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 15, 2026