

**K910062 02-10,001**Aug 16, 1991  
219 days to decisionK910062 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k910062/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Jan 9, 1991                             |
| Decision date         | Aug 16, 1991                            |
| Days to decision      | 219 days                                |
| Third-party review    | No                                      |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Laser Engineering, Inc.</b>          |
| Location       | Milford, MA, US                         |
| Contact        | ROBERT I RUDKO                          |
| 510(k) history | 18 submissions · 18 cleared · 1988-2022 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910062/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026