

**K912067 POLARIS, GYNECOLOGY INDICATIONS**Jun 16, 1992  
403 days to decisionK912067 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k912067/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | May 10, 1991                            |
| Decision date         | Jun 16, 1992                            |
| Days to decision      | 403 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Statement                               |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Pfizer Laser Systems</b>             |
| Location       | Irvine, CA, US                          |
| Contact        | COLETTE COZEAN                          |
| 510(k) history | 32 submissions · 32 cleared · 1988-1993 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912067/> 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 June 30, 2026