

K912813 SIRIUSDec 31, 1991
194 days to decisionK912813 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k912813/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jun 20, 1991 |
| Decision date | Dec 31, 1991 |
| Days to decision | 194 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912813/> 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 30, 2026