

**K961560 ECLIPSE 2000**Jan 27, 1997  
291 days to decisionK961560 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k961560/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Apr 11, 1996                            |
| Decision date         | Jan 27, 1997                            |
| Days to decision      | 291 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Cardiogenes</b>                      |
| Location       | Palo Alto, CA, US                       |
| Contact        | ANNE-MARIE DE MERLIER                   |
| 510(k) history | 20 submissions · 19 cleared · 1992-1997 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961560/> 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 July 4, 2026