

**K981627 PROTEGE II ER: YAG LASER SYSTEM AND ACCESSORIES (UPGRADE)**Jul 31, 1998  
85 days to decisionK981627 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k981627/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 7, 1998
Decision date	Jul 31, 1998
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Xintec Corporation</b>
Location	Oakland, CA, US
Contact	MARILYN M CHOU
510(k) history	26 submissions · 26 cleared · 1990-2010

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981627/>. 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 21, 2026