

**K901016 LASER-SHIELD II(TM)**Aug 29, 1990  
177 days to decisionK901016 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k901016/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 5, 1990
Decision date	Aug 29, 1990
Days to decision	177 days
Third-party review	No

**APPLICANT**

---

Company	<b>Xomed, Inc.</b>
Location	Arnold, MO, US
Contact	DONALD R BRUCE
510(k) history	82 submissions · 81 cleared · 1976-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k901016/>; 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 21, 2026