

**K882926 MODEL AU-1 ACCESSORY UNIT**Sep 9, 1988  
58 days to decisionK882926 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k882926/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 13, 1988
Decision date	Sep 9, 1988
Days to decision	58 days
Third-party review	No

**APPLICANT**

---

Company	<b>Directed Energy, Inc.</b>
Location	Walker, MI, US
Contact	EDWARD JOHANSEN
510(k) history	39 submissions · 38 cleared · 1984-1991

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k882926/> 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 22, 2026