

**K862422 MODEL 20-B CO2 LASER FOR GENERAL & PLASTIC SURGERY**Oct 2, 1986  
99 days to decisionK862422 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k862422/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 1986
Decision date	Oct 2, 1986
Days to decision	99 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/k862422/> 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 May 22, 2026