

**K862408 MODEL 8-B CO2 LASER FOR OPHTHALMIC & ORBITAL
SURG**Oct 24, 1986
121 days to decisionK862408 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k862408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 25, 1986
Decision date	Oct 24, 1986
Days to decision	121 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k862408/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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