

**K855210 SURGICAL CARBON DIOXIDE LASER SYS. #20B
ULTRALIGHT**May 2, 1986
123 days to decisionK855210 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k855210/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 30, 1985
Decision date	May 2, 1986
Days to decision	123 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/k855210/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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