

K854398 MODEL CO2 LASER SYSTEM 8BFeb 7, 1986
99 days to decisionK854398 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k854398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 31, 1985
Decision date	Feb 7, 1986
Days to decision	99 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

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