

K854387 MODEL 8A PREVIOUSLY MINI HALO CO2 LASER SYSTEMFeb 7, 1986
99 days to decisionK854387 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k854387/>**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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