

K853319 MINI-HALO(HAND-HELD) CO2 LASER SYSTEMSep 19, 1985
43 days to decisionK853319 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k853319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 7, 1985
Decision date	Sep 19, 1985
Days to decision	43 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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