

K854386 MODEL 20 PREVIOUSLY HAND-HELD CO2 LASER SYSTEM

Mar 28, 1986
148 days to decision

K854386 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k854386/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 31, 1985
Decision date	Mar 28, 1986
Days to decision	148 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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Device record: <https://www.510kdatabase.net/k854386/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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