

**K905676 MD CO2 SURGICAL LASER SYSTEM/GEN. SURGERY
AND ORTH**Apr 22, 1991
125 days to decisionK905676 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k905676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 18, 1990
Decision date	Apr 22, 1991
Days to decision	125 days
Third-party review	No

APPLICANT

Company	Laser Engineering, Inc.
Location	Milford, MA, US
Contact	ROBERT I RUDKO
510(k) history	18 submissions · 18 cleared · 1988-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905676/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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