

K870971 MODEL 20-C WITH AN SA-20B/U OPTICAL ATTACHMENTMay 26, 1987
77 days to decisionK870971 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k870971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 10, 1987
Decision date	May 26, 1987
Days to decision	77 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k870971/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 22, 2026