

**K854998 SURGICAL CO2 LASER SYSTEM #20/OPTICAL FOR ARTHROSC**May 2, 1986  
141 days to decisionK854998 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k854998/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 12, 1985
Decision date	May 2, 1986
Days to decision	141 days
Third-party review	No

**APPLICANT**

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Company	<b>Directed Energy, Inc.</b>
Location	Walker, MI, US
Contact	EDWARD JOHANSEN
510(k) history	39 submissions · 38 cleared · 1984-1991

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854998/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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