

**K870838 MODEL 10-C W/ SA-10A/U OPTICAL  
ATTACHMENT/SURG USE**May 26, 1987  
89 days to decisionK870838 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k870838/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 26, 1987
Decision date	May 26, 1987
Days to decision	89 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/k870838/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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