

**K854399 MODEL 20-B CO2 LASER SYSTEM**Feb 7, 1986  
99 days to decisionK854399 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k854399/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Oct 31, 1985                            |
| Decision date         | Feb 7, 1986                             |
| Days to decision      | 99 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/k854399/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 22, 2026