

**K101712 ENDOVASCULAR LAER VEIN SYSTEM KIT**Oct 27, 2010  
131 days to decisionK101712 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k101712/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Jun 18, 2010                            |
| Decision date         | Oct 27, 2010                            |
| Days to decision      | 131 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biolitec, Inc.</b>                   |
| Location       | East Longmeadow, MA, US                 |
| Contact        | HARRY HAYES                             |
| 510(k) history | 28 submissions · 28 cleared · 2001-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101712/> 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 June 15, 2026