

**K102755 CERALAS E/ 1470NM FIBER-COUPLED DIODE LASER FAMILY**Dec 16, 2010  
84 days to decisionK102755 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k102755/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                  |
| Submission type       | Traditional   |
| Device classification | Powered Laser Surgical Instrument (GEX)                             |
| Date received         | Sep 23, 2010  |
| Decision date         | Dec 16, 2010  |
| Days to decision      | 84 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |
| Other names           | CREALAS HPD MULTIWAVELENGTH 980NM/ 1470NM FIBER-COUPLED DIODE LASER |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biolitec, Inc.</b>                   |
| Location       | East Longmeadow, MA, US                 |
| Contact        | NANCY FOLEY                             |
| 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/k102755/> 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