

**K112013 EVOLVE(R) HPD 980/1470NM MULTIWAVELENGTH
DIODE LASER**Jan 13, 2012
183 days to decisionK112013 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k112013/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Jul 14, 2011 |
| Decision date | Jan 13, 2012 |
| Days to decision | 183 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112013/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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