

**K031140 WATERLASE**Jul 7, 2004  
454 days to decisionK031140 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k031140/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received         | Apr 10, 2003                            |
| Decision date         | Jul 7, 2004                             |
| Days to decision      | 454 days                                |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biolase Technology, Inc.</b>         |
| Location       | Clemente, CA, US                        |
| Contact        | IOANA M RIZOIU                          |
| 510(k) history | 31 submissions · 31 cleared · 1995-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031140/> 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 9, 2026