

K083927 WATERLASE MDOct 1, 2009
274 days to decisionK083927 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083927/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Dec 31, 2008 |
| Decision date | Oct 1, 2009 |
| Days to decision | 274 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biolase Technology, Inc. |
| Location | Clemente, CA, US |
| Contact | IOANNA RIZOU |
| 510(k) history | 31 submissions · 31 cleared · 1995-2013 |

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