FDA 510(k) Premarket Notification

# K031140 WATERLASE

**CLEARED**

Jul 7, 2004
454 days to decision

K031140 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k031140/

## SUBMISSION DETAILS

| | |
|---|---|
| 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

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