FDA 510(k) Premarket Notification

K090181 WATERLASE MD

CLEARED

Feb 11, 2009
16 days to decision

K090181 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k090181/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 26, 2009
Decision date	Feb 11, 2009
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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