FDA 510(k) Premarket Notification

K003385 TWILITE, TWILITE WHITE

CLEARED

Jan 25, 2001
86 days to decision

K003385 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003385/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 31, 2000
Decision date	Jan 25, 2001
Days to decision	86 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