

K971207 SOFTLIGHT Q-SWITCHED (ND:YAG) LASERMay 13, 1998
412 days to decisionK971207 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k971207/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 27, 1997
Decision date	May 13, 1998
Days to decision	412 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermolase Corp.
Location	San Diego, CA, US
Contact	ROBERT VAN OSDEL
510(k) history	3 submissions · 3 cleared · 1995-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971207/> Data sourced from FDA 510(k) public records (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. - Generated July 3, 2026