

K050382 AFFINITY QS Q-SWITCHED ND:YAG LASER SYSTEMSep 14, 2005
211 days to decisionK050382 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k050382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 15, 2005
Decision date	Sep 14, 2005
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cynosure, Inc.
Location	Bedford, MA, US
Contact	GEORGE CHO
510(k) history	98 submissions · 98 cleared · 1992-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050382/> 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 June 18, 2026