

K970017 NIDEK CYBERSCANMar 18, 1997
75 days to decisionK970017 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970017/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 2, 1997
Decision date	Mar 18, 1997
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nidek, Inc.
Location	Mchenry, IL, US
Contact	KEN KATO
510(k) history	77 submissions · 77 cleared · 1983-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970017/> 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 May 19, 2026