FDA 510(k) Premarket Notification

K970017 NIDEK CYBERSCAN

CLEARED

Mar 18, 1997
75 days to decision

K970017 · Product code: **GEX** · General & Plastic Surgery
Source: 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