FDA 510(k) Premarket Notification

K900165 NIDEK, INC. BIO-DC LASER DELIVERY SYSTEM

CLEARED

Mar 22, 1990
69 days to decision

K900165 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k900165/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 12, 1990
Decision date	Mar 22, 1990
Days to decision	69 days
Third-party review	No

APPLICANT

Company	**Nidek, Inc.**
Location	Mchenry, IL, US
Contact	MCCOMB, PH.D.
510(k) history	77 submissions · 77 cleared · 1983-2005