FDA 510(k) Premarket Notification

K900890 NIDEK MODEL AKC-8000 OPHTHALMIC LASER PHOTOCOAGULA

CLEARED

Sep 10, 1990
195 days to decision

K900890 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k900890/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 27, 1990
Decision date	Sep 10, 1990
Days to decision	195 days
Third-party review	No

APPLICANT

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