

K973828 PRIMA KTP LASER SYSTEMJan 5, 1998
90 days to decisionK973828 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k973828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 7, 1997
Decision date	Jan 5, 1998
Days to decision	90 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

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