FDA 510(k) Premarket Notification

K914089 SHARPLAN SHARPLASE FAMILY OF HANDSWITCHED ND:YAG

CLEARED

Dec 6, 1991
86 days to decision

K914089 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k914089/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 11, 1991
Decision date	Dec 6, 1991
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sharplan Lasers, Inc.**
Location	Allendale, NJ, US
Contact	DOUGLASS MEAD
510(k) history	78 submissions · 78 cleared · 1986-1997