FDA 510(k) Premarket Notification

K913037 SHARPLAN SHARPLASE FAMILY ND:YAG SCULPTED FIBERS

CLEARED

Sep 6, 1991
59 days to decision

K913037 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k913037/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 9, 1991
Decision date	Sep 6, 1991
Days to decision	59 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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