FDA 510(k) Premarket Notification

K891088 MODIFIED LABELING PACKAGING SHARPLAN 2100 STERILE

CLEARED

Mar 17, 1989
71 days to decision

K891088 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k891088/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 5, 1989
Decision date	Mar 17, 1989
Days to decision	71 days
Third-party review	No

APPLICANT

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