FDA 510(k) Premarket Notification

K933211 D'AMICO\PEYMAN FLUTED ENDOPROBE

CLEARED

Apr 19, 1994
350 days to decision

K933211 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k933211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 4, 1993
Decision date	Apr 19, 1994
Days to decision	350 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Iriderm Div.**
Location	Mountain View, CA, US
Contact	THEODORE A BOUTACOFF
510(k) history	10 submissions · 10 cleared · 1989-1997