FDA 510(k) Premarket Notification

K901638 MODIFIED COMBOLASER 5050 & NEW MODEL 5050 VER. 33

CLEARED

Jun 27, 1990
79 days to decision

K901638 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k901638/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 9, 1990
Decision date	Jun 27, 1990
Days to decision	79 days
Third-party review	No

APPLICANT

Company	**Lasermatic, Inc.**
Location	Dallas, TX, US
Contact	TOBY FULLER
510(k) history	8 submissions · 8 cleared · 1988-1991