FDA 510(k) Premarket Notification

K954934 CANDELA SPTL LONG PULSE/TUNABLE PULSED DYE LASE

CLEARED

Feb 2, 1996
98 days to decision

K954934 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k954934/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 27, 1995
Decision date	Feb 2, 1996
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Candela Laser Corp.**
Location	Wayland, MA, US
Contact	JONATHAN S KAHAN
510(k) history	43 submissions · 43 cleared · 1988-1996