

**K934706 CANDELA PLTL-1 LASER SYSTEM: PIGMENTED
LESION LASER AND TATULAZR**Apr 29, 1994
211 days to decisionK934706 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k934706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 1993
Decision date	Apr 29, 1994
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Candela Laser Corp.
Location	Wayland, MA, US
Contact	THOMAS R VARRICCHIONE, MBA, RRT
510(k) history	43 submissions · 43 cleared · 1988-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934706/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026