

K882243 SPTL-1 PULSED DYE LASERJul 5, 1988
35 days to decisionK882243 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k882243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 31, 1988
Decision date	Jul 5, 1988
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Candela Laser Corp.
Location	Wayland, MA, US
Contact	GEORGE CHO
510(k) history	43 submissions · 43 cleared · 1988-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882243/>; 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