

K861179 CANDELA MODEL SPT-1, PULSED DYE LASERNov 20, 1986
234 days to decisionK861179 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k861179/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 31, 1986
Decision date	Nov 20, 1986
Days to decision	234 days
Third-party review	No

APPLICANT

Company	Candela Corp.
Location	Natick, MA, US
Contact	RONALD L CARROLL
510(k) history	48 submissions · 48 cleared · 1986-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861179/>; 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 18, 2026