

**K892516 CANDELA PLDL-1 PULSED DYE LASER**Jun 15, 1989  
65 days to decisionK892516 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k892516/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 11, 1989
Decision date	Jun 15, 1989
Days to decision	65 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892516/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026