

**K900165 NIDEK, INC. BIO-DC LASER DELIVERY SYSTEM**Mar 22, 1990  
69 days to decisionK900165 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k900165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 12, 1990
Decision date	Mar 22, 1990
Days to decision	69 days
Third-party review	No

**APPLICANT**

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Company	<b>Nidek, Inc.</b>
Location	Mchenry, IL, US
Contact	MCCOMB, PH.D.
510(k) history	77 submissions · 77 cleared · 1983-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k900165/>; 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 May 19, 2026