

K990914 POLARIS DIODE LASER SYSTEM AND ACCESSORIESJul 30, 1999
134 days to decisionK990914 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k990914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 18, 1999
Decision date	Jul 30, 1999
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xintec Corporation
Location	Oakland, CA, US
Contact	MARILYN M CHOU
510(k) history	26 submissions · 26 cleared · 1990-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990914/> 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 21, 2026