

K950313 KAPLAN PENDULASER 115 - A 15W CO2 SURGICAL LASERMar 24, 1995
57 days to decisionK950313 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k950313/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 26, 1995
Decision date	Mar 24, 1995
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optomedic Medical Technologies , Ltd.
Location	Rockville, MD, US
Contact	ALEX HAREL
510(k) history	2 submissions · 2 cleared · 1995-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950313/> 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 July 4, 2026