

**K980398 KAPLAN PENDULASER 115 SURGICAL LASER WITH OPTOSCAN II**

Sep 22, 1998  
232 days to decision

K980398 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k980398/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 2, 1998
Decision date	Sep 22, 1998
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optomedic Medical Technologies , Ltd.</b>
Location	Rockville, MD, US
Contact	WHIT ATHEY
510(k) history	2 submissions · 2 cleared · 1995-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k980398/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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