

**K971648 SHARPLAN ERBIUM: YAG LASER (4020)**Jul 23, 1997  
79 days to decisionK971648 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k971648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 5, 1997
Decision date	Jul 23, 1997
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sharplan Lasers, Inc.</b>
Location	Allendale, NJ, US
Contact	GEORGE J HATTUB
510(k) history	78 submissions · 78 cleared · 1986-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971648/> 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 20, 2026