

**K965015 TOPAZ 30 SURGICAL LASER SYSTEM**Mar 14, 1997  
88 days to decisionK965015 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k965015/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 16, 1996
Decision date	Mar 14, 1997
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Esc Medical Systems, Inc.</b>
Location	Needham, MA, US
Contact	HILLEL BACHRACH
510(k) history	3 submissions · 3 cleared · 1997-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965015/> 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 July 4, 2026