

**K934895 GLASSMAN SILICONE CATHETER**Oct 13, 1994  
373 days to decisionK934895 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k934895/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Oct 5, 1993
Decision date	Oct 13, 1994
Days to decision	373 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Axiom Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	RIDWAN HARDY
510(k) history	28 submissions · 28 cleared · 1977-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934895/> 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 25, 2026