

**K954535 ELASTYREN HYPOALLERGENIC SURGICAL GLOVES**Dec 11, 1995  
73 days to decisionK954535 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k954535/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon&apos;s Gloves (KGO)
Date received	Sep 29, 1995
Decision date	Dec 11, 1995
Days to decision	73 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Eci Medical Technologies, Inc.</b>
Location	Richmondhill, Ontario, CA
Contact	MICHAEL FORER
510(k) history	9 submissions · 9 cleared · 1995-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954535/> 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 2, 2026