

**K946291 ELASTYREN(R) PATIENT EXAMINATION GLOVES**Feb 14, 1995  
49 days to decisionK946291 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k946291/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 27, 1994
Decision date	Feb 14, 1995
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946291/> 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