

**K931491 SIME HEALTH SIME HYPOALLERGENIC**Oct 15, 1993  
204 days to decisionK931491 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k931491/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 25, 1993
Decision date	Oct 15, 1993
Days to decision	204 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sime Health, Ltd.</b>
Location	Seattle, WA, US
Contact	HELEN MARIESKIND
510(k) history	11 submissions · 11 cleared · 1991-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931491/> 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 June 29, 2026